# ANNUAL REPORT 2012

For the year ended March 31, 2012

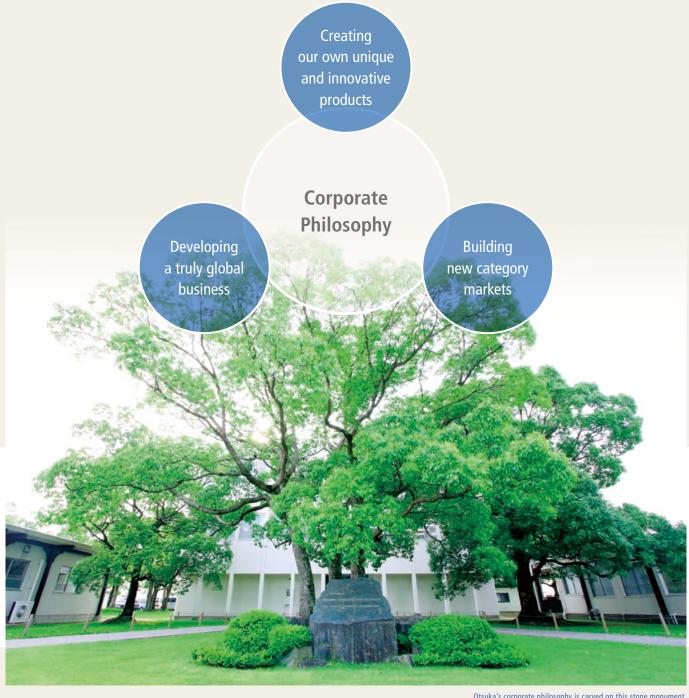




Otsuka-people creating new products for better health worldwide

## Corporate Philosophy

## Otsuka-people creating new products for better health worldwide



The Otsuka Group is a global healthcare group operating under the corporate philosophy of "contributing to the health of people around the world." The Company takes an integrated approach to healthcare for the whole body, building its business on two main strategic pillars: the pharmaceutical business, which contributes to the diagnosis and treatment of disease, and the nutraceutical\* business, which supports the maintenance and improvement of day-to-day well-being. Every day, Otsuka employees—in 25 countries and regions around the world—seek new solutions to health needs, with the mission of making humanity's universal wish for good health a reality for everyone.

\*nutraceuticals = nutrition + pharmaceuticals

## Monuments in Tokushima, the birth place of the Otsuka Group



#### Giant Tomato Trees

As a result of efforts to make maximum use of the potential of plants using hydroponic cultivation, these "trees," which cover the entire ceiling of the hall, can produce 10,000 or more tomatoes a year, compared with conventional tomato plants grown in soil. These "tomato trees" hold the message that it is possible to free oneself from preconceived notions and demonstrate one's unlimited potential.

#### Bent Giant Cedar

This piece of art consists of a giant cedar trunk—which one would not expect to see in such a position: bent low, as if in a deep bow—with another Japanese cedar trunk placed on top and fixed stably at a single point. This sculpture speaks of the importance of breaking down preconceptions and changing one's way of thinking.

#### Floating Stone

This water garden features large stones appearing to miraculously float on the water. The garden was created to capture people's interest, enrich the mind, and cultivate the ability to think. The round stones express Otsuka's love of humanity and its wish for people's health.



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#### Cover picture:

Human Resource Development Institute, established in 1988 in Tokushima, Japan, a training facility to promote employee awareness of Otsuka's ethos of creating innovative products.

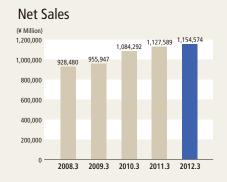
\*Figures up to FY2007 represent the consolidated results of Otsuka Pharmaceutical Co., Ltd.

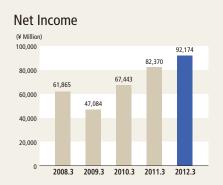
			Millions of yen			Millions of U.S. dollars (Note 1)
	2008.3 (FY2007)	2009.3 (FY2008)	2010.3 (FY2009)	2011.3 (FY2010) (Notes 3 and 4)	2012.3 (FY2011)	2012.3 (FY2011)
Net sales	¥928,480	<b>¥</b> 955,947	¥1,084,292	¥1,127,589	¥1,154,574	\$14,048
Operating income	118,254	91,520	98,481	126,292	148,662	1,809
Net income	61,865	47,084	67,443	82,370	92,174	1,121
Per share of common stock-basic (Yen and U.S. dollars)	4,693	2,727	143.51	164.52	165.20	2.01
Per share of common stock-diluted (Yen and U.S. dollars)	4,690	2,725	143.47	164.40	164.73	2.00
Dividends per share (Yen and U.S. dollars)	300	250	12.50	28.00	45.00	0.55
Capital expenditures	36,852	35,438	62,456	44,793	43,302	527
Depreciation and amortization	32,283	40,296	46,626	48,097	48,062	585
R&D expenses	101,804	135,900	151,849	164,671	159,230	1,937
Total assets	1,033,976	1,298,790	1,458,376	1,589,717	1,666,767	20,279
Net assets (Note 2)	731,782	863,816	948,457	1,163,326	1,222,765	14,877
Return on equity	13.0%	7.2%	7.7%	7.9%	7.8%	7.8%
Equity ratio	48.6%	62.3%	64.2%	72.4%	72.5%	72.5%
Number of shares issued	13,582,462	23,518,869	519,156,817	557,835,617	557,835,617	557,835,617
Number of employees	20,036	22,928	24,589	25,188	24,595	24,595

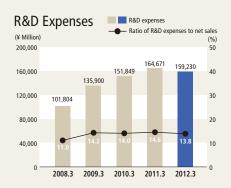
#### Notes

- 1. Financial information in U.S. dollars has been converted at US\$1=¥82.19, the rate of March 31, 2012.
- 2. Minority interests have been included in net assets.
- 3. Effective from FY2010, the Company applied "Accounting Standard for Earnings Per Share" (ASBJ Statement No. 2 revised on June 30, 2010), "Guidance on Accounting Standard for Earnings Per Share" (ASBJ PITF No. 9 revised on June 30, 2010). Basic and diluted net incomes per share (EPS) for FY2010 have been adjusted retrospectively.
- 4. From FY2011, the Company changed its method of accounting for translating revenue and expense accounts of foreign subsidiaries and affiliated companies and its method of presentation for up-front licensing payments received. The FY2010 figures have been adjusted retrospectively to apply the changes in accounting policy and method of presentation described above. The cumulative effect of these changes up to FY2009 is reflected in the FY2010 beginning equity balances.

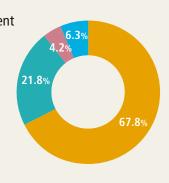
the FY2010 beginning equity balances.
\*On June 30, 2009, Otsuka Holdings Co., Ltd conducted a one-for-twenty stock split.

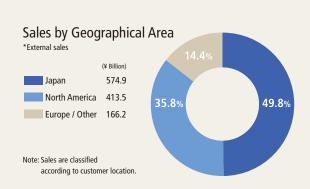












# Delivering Further Growth by Offering Creative, "Uniquely Otsuka" Products

First of all, I would like to express my sincere appreciation for your understanding and loyal support for the Otsuka Group's business endeavors. We look forward to your continued support.

Otsuka Holdings was listed on the Tokyo Stock Exchange in December 2010. In May 2012, we issued financial statements and a progress report for fiscal 2011 (the year ended March 31, 2012), the first full fiscal year after our listing.

In May 2011, we released our First Medium-Term

Management Plan and presented performance targets for
fiscal 2013 (ending March 31, 2014), the final year of the
plan, and priority measures designed to achieve them. In
fiscal 2011, the first year of the period covered by the plan,
we achieved an increase in both revenue and profit by
steadfastly implementing the priority measures despite harsh
external factors such as the earthquake disaster and the
effects of the persistently strong yen.

In the pharmaceutical business, the continued global increase in sales of *ABILIFY*, which is currently available in 60 markets worldwide, drove performance. In addition, steady growth of the new drugs *Aloxi*, *Abraxane*, *E Keppra*, and *SAMSCA* in Japan as well as strong results for clinical nutrition products, centered on expansion of *ELNEOPA*, also contributed to performance.

In the nutraceutical business, sales in Japan of *Pocari Sweat*, which is sold in 17 markets, did not reach the level seen in fiscal 2010, when it benefitted from a very hot summer. However, sales volume outside Japan remained strong, growing by more than 20% year on year. Moreover, efforts aimed at improving profitability, including ongoing review of our cost structure, paid off as we achieved profit growth.

As a strategic move for the future, in the pharmaceutical business we signed a global alliance agreement concerning the central nervous system area with H. Lundbeck A/S of



Denmark in November 2011. Through this tie-up, we aim to achieve long-term growth in the central nervous system area. We are also working on the development of new drugs to address unmet medical needs, including a treatment for tuberculosis, which has not seen the approval of a new drug in 40 years. Furthermore, in November 2011, the Group acquired KiSCO Co., Ltd., a medical devices company specializing in the orthopedic surgery field, and in December it acquired a stake in Era Endoscopy S.r.l. of Italy, an innovator in self-propelled robotic colonoscopy, as part of efforts to build the medical device business into one of the Otsuka Group's core businesses. Going forward, we plan to develop the medical device business mainly in Japan and Asia.

In the nutraceutical business, we are working on the development and global expansion of delicious products that make full use of the rich nutrition in soy as a solution to various health and environmental issues faced by people today, under the concept of "Soylution." In April 2012, we launched the healthy soy snack SoyCarat, the third Soylution product after the fruit soy bar SOYJOY and the carbonated soy beverage SOYSH. Going forward, we will continue to propose new "Soylutions."

We appreciate and look forward to your further support as the Otsuka Group makes a concerted effort to make further dynamic progress toward global growth.

> Tatsuo Higuchi President and Representative Director, CEO Otsuka Holdings Co., Ltd.

Total techi

The Otsuka Group has two core businesses: the pharmaceutical business and the nutraceutical business.

The pharmaceutical business provides comprehensive support for human health, meeting the entire range of medical needs, from diagnosis to treatment of disease. The nutraceutical business helps people to maintain and improve their daily health and well-being.

By carrying out its operations in these two core businesses, the Otsuka Group contributes to the health of people worldwide.

## Developing businesses that encompass every healthcare theme

as a global healthcare company that pursues excellence in manufacturing

### **Pharmaceutical business**

From diagnosis to treatment of diseases

- ABILIFY driving earnings growth
- •Leading company in the I.V. solution and oncology fields
- •Taking on the challenge of exploring new fields in drug discovery to address unmet medical needs



High profitability and growth potential



## **Nutraceutical business**

Maintain and improve daily health and well-being

- Create unique and innovative products
- Build new market categories
- Establish powerful brand equity





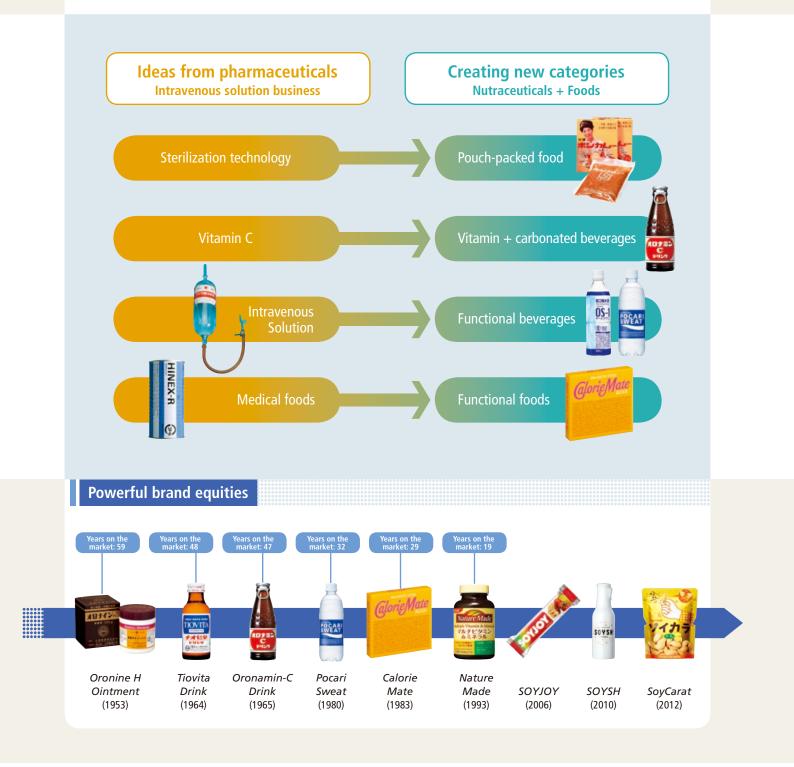
Stable revenue platform

## Contribute to health through two mainstay businesses Develop global business of this twin-engine business portfolio

- •Proprietary production and sales platforms in each key region
- Wealth of experience in cultivating markets
   (Intravenous solutions → nutraceuticals → pharmaceuticals)

## **Synergy of Pharmaceuticals and Nutraceuticals**

Otsuka's products are developed by leveraging the Company's experience and knowhow in the intravenous solutions business and in clinical nutrition, which have been the Group's main business areas since its foundation. Our products have created new markets thanks to their originality, and many of them have retained their brand strength as long-selling products.



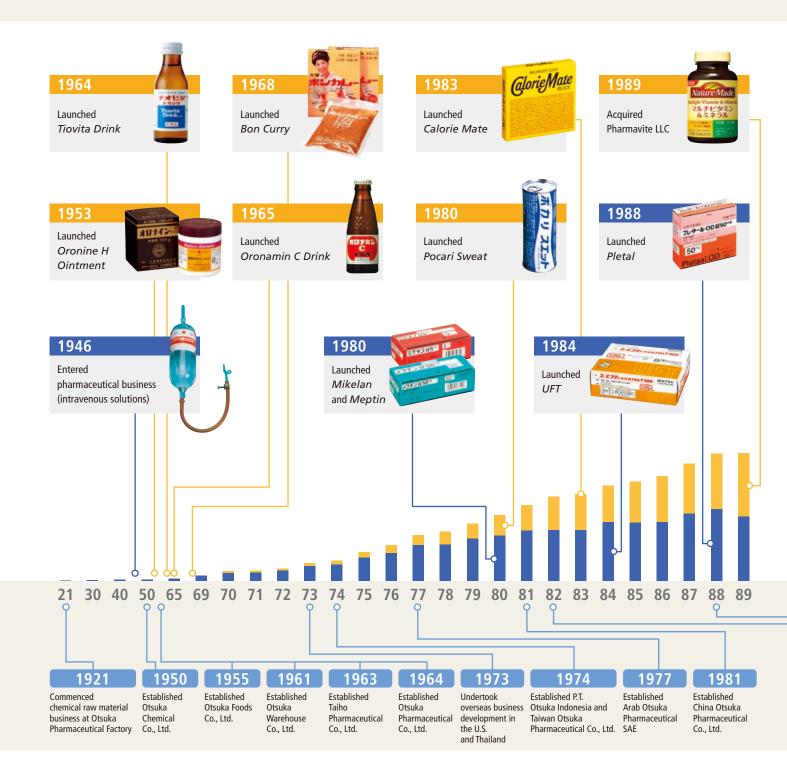
1900

## Foundation phase

Started as a chemical raw materials manufacturer in Naruto, Tokushima Prefecture, Japan.

## **Growth phase**

Opened the Tokushima Research Institute with the aim of in-house drug development. Numerous products in the nutraceutical segment, such as *Oronamin C*, *Pocari Sweat*, and *Calorie Mate*, opened up new markets, diversifying the Group's business.



## 2000

## International business development phase

## **Expansion phase**

Established bases outside Japan and started aggressive global expansion.

Pursuing further global growth.



Otsuka Holdings established its First Medium-Term Management Plan and regards the three years covered by the plan—fiscal 2011 to fiscal 2013—as the time to develop a world-class structure as a global healthcare company with the two mainstay businesses of pharmaceuticals and nutraceuticals.

The main progress made during the first year is described below.

Principal Measures Development of innovative proprietary pharmaceuticals

Profit structure improvement aimed at securing profit growth in the nutraceutical business

Next-generation business incubation through strategic alliances and other measures

Progress on Principal Measures

Development of innovative proprietary pharmaceuticals

Principal Measures Next-generation business incubation through strategic alliances and other measures





As part of the effort to fulfill these measures in the medium-term management plan, Otsuka Pharmaceutical signed a global alliance agreement in the field of the central nervous system (CNS) in November 2011 with Danish company Lundbeck, a global leader in the field. More evolved development of the CNS business can be expected as Lundbeck, which is experienced in depression and anxiety disorder treatment, and Otsuka Pharmaceutical, which has a steady track record in antipsychotic drugs, cooperate based on the agreement. The following are the two main points of the agreement:

- Lundbeck agreed to pay up to approximately USD\$1.8 billion to Otsuka Pharmaceutical to work on the co-development and commercialization
  of aripiprazole\*1 intramuscular depot (once monthly) formulation and OPC-34712.
- The two companies will carry out co-development and commercialization of up to five compounds: up to three new compounds currently under research and development by Lundbeck for CNS disorders, along with aripiprazole intramuscular depot formulation and OPC-34712.

This alliance will enable Otsuka Pharmaceutical to cover many regions around the world including Lundbeck's main territory in Europe as well as its sales outlets in South America, Oceania, \*2 and the BRICs, \*3 in addition to existing channels in Japan, the U.S., and Asia. Furthermore, the alliance can be expected to support long-term growth in the CNS field for both companies as it will lead to co-development and co-marketing of three new compounds being researched by Lundbeck.

\*1. Aripiprazole is the generic name of the active ingredient of ABILIFY \*2. Australia, New Zealand, and other countries. \*3. Brazil, Russia, India, and China.

#### **Geographical Strategy**

- Employ Otsuka Pharmaceutical's strength in Japan, the U.S., and Asia
- Employ Lundbeck's strength in Europe, South America, and emerging countries
- Geographical strategy to expand business by sharing global experience (clinical development, regulatory affairs, commercialization, drug price negotiations, etc.)

#### **Research Strategy**

- Employ Otsuka Pharmaceutical's strength in the antipsychotic field
- Employ Lundbeck's expertise in the field of antidepressants and antianxiety drugs
- Fresh approaches enable us to improve existing value and take on the challenges of new fields

#### **CNS Strategy**

- Otsuka Pharmaceutical: Enhances next-generation portfolio in the CNS field
- Lundbeck: Covers a wide range of diseases, from schizophrenia to Alzheimer's disease

## Similar Corporate Cultures

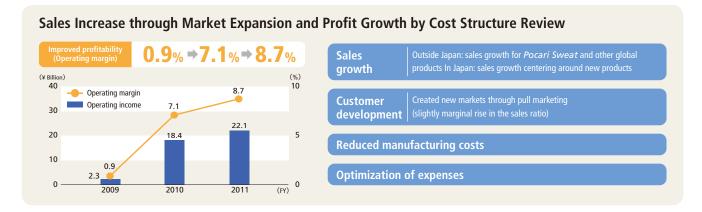
- Enable the sharing of values that create an environment fostering success
- Possess the ability to respect each other's traditions and share goals

## Profit Structure Improvement Aimed at Securing Profit Growth in the Nutraceutical Business

The medium-term management plan calls for securing profit growth in the nutraceutical business. As indicated in the table below, Otsuka made aggressive efforts to expand the market by opening up new areas with *Pocari Sweat* and other global products, and to increase sales by creating new markets with new product launches. Meanwhile, revenue was improved by pushing the reduction of production costs and the optimization of expenses and through the balanced allocation of resources for creating new markets.







## Performance Targets and Progress Under the First Medium-Term Management Plan

Performance of fiscal 2011 is shown in the table below. For more details on performance, see the Financial Highlights and business and financial reviews.

#### Performance targets and fiscal 2011 progress

(¥ Billion)	FY2010 actual	FY2013 plan	CAGR	FY2011 actual	Year-on-year change
Net sales	1,127.6	1,330.0	6.9%	1,154.6	2.4%
Ratio of overseas sales to net sales	49.0%	50.0%		50.2%	
R&D expenses	164.7	200.0	6.7%	159.2	(-3.3%)
vs. net sales	14.6%	15.0%		13.8%	
Operating income	126.3	200.0	19.4%	148.7	17.7%
vs. net sales	11.2%	15.0%		12.9%	
Net income	82.4	130.0	17.1%	92.2	11.9%
Earnings per share	164.51 yen	230 yen	12.4%	165.20 yen	
Return on equity	7.9%	At least 10%		7.8%	

Assumptions regarding foreign currency exchange rates for the First Medium-Term Management Plan:

USD\$1 = ¥85; Euro 1 = ¥115 Actual rates for fiscal 2010: USD\$1 = ¥87.79; Euro 1 = ¥116.27

Actual rates for fiscal 2011: USD\$1 = \times \text{Y9.79}; Euro 1 = \times \text{Y111.12}

Performance for fiscal 2010 has been retroactively adjusted following changes in accounting policy.

## Outlook for Fiscal 2012 (Second Year of the First Medium-Term Management Plan)

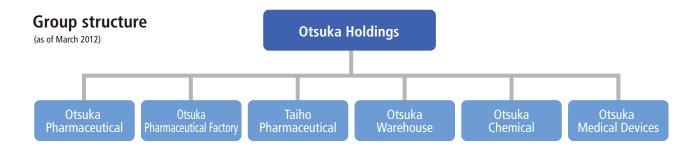
In the pharmaceutical business, sales of *ABILIFY* are expected to hold steady, and growth of new products such as *Aloxi*, *Abraxane*, *E Keppra*, and *SAMSCA* is expected to drive sales growth. Approval of aripiprazole intramascular depot formulation in the U.S. is also anticipated. Meanwhile, R&D expenses will increase, with progress in the state of development of compounds in the CNS field, such as the next-generation antipsychotic OPC-34712, but this is a necessary investment for future growth. In the nutraceutical business, efforts will be made to expand sales and improve the profit structure, through the continued promotion of product value for new products such as *SoyCarat* as well as flagship products such as *Pocari Sweat*.

Fiscal 2012 performance forecast

(¥ Billion)	FY2011 actual	FY2012 (forecast)	Year-on-year change (forecast)		
			Amount change	Percent change	
Net sales	1,154.6	1,200.0	45.4	3.9%	
Operating income	148.7	165.0	16.3	11.0%	
Ordinary income	152.1	170.0	17.9	11.8%	
Net income	92.2	108.0	15.8	17.2%	
R&D expenses	159.2	170.0	10.8	6.8%	
EPS	165.20 yen	193.60 yen			
Dividend per share	45 yen	58 yen			

Actual rates for fiscal 2011: USD\$1 =  $\pm$ 79.79; Euro 1 =  $\pm$ 111.12 Estimated rate for fiscal 2012: USD\$1 =  $\pm$ 75; Euro 1 =  $\pm$ 102

Otsuka Holdings Co., Ltd. was established on July 8, 2008 as a holding company for the Otsuka Group to improve overall Group corporate value. Otsuka Holdings will support the sustainable growth of Group companies, maximize the Group's synergies by integrating management resources, increase management efficiency, and empower employees and organizations.



## Otsuka Pharmaceutical Co., Ltd.

Otsuka Pharmaceutical was established in 1964. In keeping with its corporate philosophy of "contributing to the health of people worldwide," the company's aim is to create value on a global scale. Driving its two strategic businesses of "pharmaceuticals to treat illness" and "nutraceuticals to prevent illness and sustain everyday health," the company is engaged in the research, development, manufacturing, and marketing of unique, innovative products. It continually pursues these challenges in the spirit of a big venture company.

## Otsuka Pharmaceutical Factory, Inc.

Otsuka Pharmaceutical Factory was the first company in the Otsuka Group founded by Busaburo Otsuka in 1921. Specializing in intravenous solutions, the company has developed products to suit the treatment of a range of different conditions and dose regimens. It initiated the development and spread of plastic containers and packaging, dual-chamber bags for the administration of high-calorie infusion solutions, and kits for aseptic delivery of antibiotic solutions, thereby making a significant contribution to advances in intravenous solution therapy and product technology both in and outside Japan. Otsuka Pharmaceutical Factory aims to be a leading company and the best partner of both patients and healthcare professionals in the field of clinical nutrition.

## Taiho Pharmaceutical Co., Ltd.

Taiho Pharmaceutical was established in 1963. Based on its corporate philosophy—"We strive to improve human health and contribute to a society enriched by smiles"—it has embraced the challenge of developing original pharmaceuticals that can contribute to society while aspiring to be an agile specialty pharmaceutical company trusted the world over. In its healthcare business as well, the company strives to create and nurture unique brands that inspire consumer loyalty over the long term. Taiho Pharmaceutical also addresses environmental issues and engages in an extensive range of community projects.

## Otsuka Warehouse Co., Ltd.

Since its establishment in 1961, Otsuka Warehouse has engaged in the distribution of pharmaceuticals as well as of food and beverages. The company is well recognized for its track record in safety and security, a product of its history and experience. As a member of the global community, Otsuka Warehouse promotes environment-friendly distribution methods such as the introduction of modal shift\* and joint distribution to reduce CO<sub>2</sub> emissions. In its role as a "Logistics Services Provider," the company strives to create new dimensions in the distribution business to leave a prosperous and beautiful environment for the next generation.

## Otsuka Chemical Co., Ltd.

Established in 1950 as Otsuka Chemical and Medical Products, Otsuka Chemical provides society with materials and products that meet a wide range of needs. It also aspires to be a company that contributes to health, the environment, and an enriched quality of life through chemical and beverage businesses. Otsuka Chemical will continue in its efforts to grow as a trusted organization, valued by society, that makes a positive contribution to customers as a manufacturer built upon proprietary technology development.

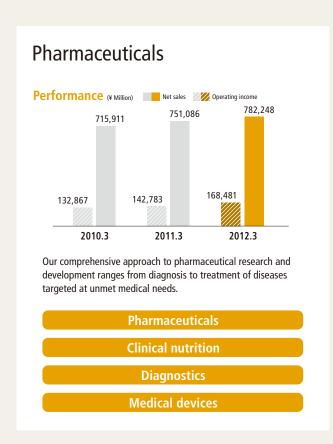
## Otsuka Medical Devices Co., Ltd.

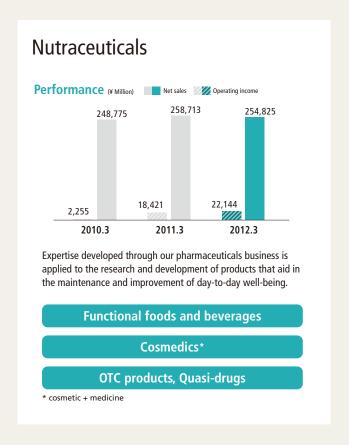
Otsuka Medical Devices was established in February 2011 as a holding company to oversee the Otsuka Group's medical devices business. Its objective is to grow the business, which currently operates mainly in Asia, including Japan and China, into one of the Group's core businesses. Otsuka Medical Devices will pursue further growth for the Group by meeting new medical needs through the concentration of the Group's experience and expertise in the medical devices business.

Changing the mode of transport from truck and air freight to ships, trains and other modes that generate less CO<sub>2</sub> emission.

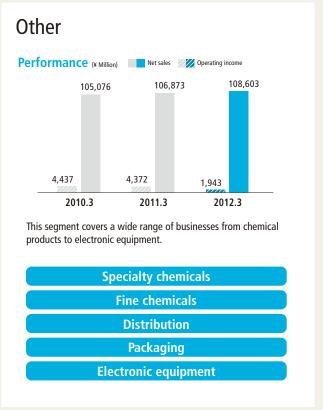
## **Business Segments**

The Otsuka Group conducts business in four main areas of activity: pharmaceuticals, nutraceuticals, consumer products, and other businesses.









Note: Intersegment sales are included.

## Pharmaceutical Segment

## **Pharmaceutical Segment Overview**

The Otsuka Group's Pharmaceutical Business focuses on the priority areas of the central nervous system and oncology in order to address unmet medical needs. Furthermore, the Group is engaged in a wide range of fields and businesses, including the cardiovascular system, gastroenterology, ophthalmology, diagnostics, and the clinical nutrition and medical device businesses in order to provide comprehensive healthcare solutions ranging from diagnosis to the treatment of disease.



Pharmaceuticals	Central nervous system, Oncology, Cardiovascular system, Gastroenterology, Respiratory system, Infectious disease, Ophthalmology, Dermatology, Allergies, Urology
Clinical nutrition	Intravenous solutions, Enteral nutrition, Contract manufacturing
Diagnostics	Influenza diagnostics agents, Helicobacter pylori test kit, other products
Medical devices	Apheresis device for leukocyte adsorption, Drug-eluting stents, other products

## Marketing activities

Otsuka Pharmaceutical, Taiho Pharmaceutical, and Otsuka Pharmaceutical Factory operate globally, primarily in the pharmaceutical business.

### Core products

Brand name (generic name)	Therapeutic category	Major indications	Company
ABILIFY (aripiprazole)	Antipsychotic	Schizophrenia, bipolar disorder (mania)	Otsuka Pharmaceutical
Pletaal/Pletal (cilostazol)	Antiplatelet agent	Improvement of ischemic symptoms including ulcers, pain, and coldness associated with chronic arterial obstruction, prevention of recurrent cerebral infarction	Otsuka Pharmaceutical
Mucosta (rebamipide)	Antigastritis and antigastric ulcer agent	Gastritis, gastric ulcers	Otsuka Pharmaceutical
TS-1 (tegafur, gimeracil, oteracil potassium)	Antimetabolite	Gastric cancer, head and neck cancer, colorectal cancer, non-small cell lung cancer, pancreatic cancer, bile duct cancer, inoperable or recurrent breast cancer	Taiho Pharmaceutical
UFT (tegafur, uracil)	Antimetabolite	Gastric cancer, head and neck cancer, colorectal cancer, liver cancer, pancreatic cancer, cancer of the gallbladder/bile duct, lung cancer, breast cancer, bladder cancer, prostate cancer, cervical cancer	Taiho Pharmaceutical
Uzel (calcium folinate)	Reduced folic acid formulation	Folinate and tegafur/uracil combination therapy enhances efficacy of tegafur-uracil in treating colorectal cancer	Taiho Pharmaceutical

## Pharmaceutical Business

## **Central Nervous System**

Sales of the antipsychotic agent *ABILIFY*, which is sold in 60 markets worldwide, have continued to expand on a global basis. Global sales in fiscal 2011 were ¥411.6 billion, an increase of 4.8% year on year. The product is now one of the top ten drugs worldwide in terms of sales.\*<sup>1</sup>

In the U.S., *ABILIFY* was increasingly prescribed for adjunctive therapy in major depressive disorder, supporting sales growth to US\$3.96 billion, up 12.7% year on year.

In Europe, healthcare spending was cut back across the region due to fiscal austerity policies, leading to a slump in the market for atypical antipsychotic agents. Despite this general trend, however, sales of *ABILIFY* in Europe grew at a double-digit pace driven by increasing prescriptions for the treatment of the manic symptoms of bipolar disorder.

Sales increased in Asia as a result of growth in prescriptions in China following *ABILIFY*'s inclusion in the country's national medical insurance system, and growth in prescriptions for the treatment of major depressive disorder in South Korea, Indonesia, and Taiwan.

In Japan, sales growth was assisted by further strengthening of information provision regarding the treatment of schizophrenia, as well as an additional indication for the treatment of the manic symptoms of bipolar disorder. In May 2012,



ABILIFY OD Tablets, a new formulation that can be taken without water, was launched in Japan.

The antiepileptic drug *E Keppra*, which is co-promoted in Japan with UCB Japan, has now been on the market for one year. Sales grew following its approval for long-term prescriptions in October 2011.

As part of efforts to accelerate growth in the central nervous system area, Otsuka Pharmaceutical signed an alliance agreement in November 2011 with H. Lundbeck A/S ("Lundbeck") of Denmark, a global leader in this field, for co-development and co-commercialization of aripiprazole intramuscular depot formulation (once-monthly injection) and OPC-34712.

This alliance is aimed at maximizing the medical and commercial value of both companies in the area of the central nervous system. The alliance has also made it possible for Otsuka Pharmaceutical to expand beyond Japan, Asia, and the U.S. via Lundbeck's existing marketing channels in Europe and emerging countries. Under the terms of the agreement, the Company has received an upfront payment of US\$200 million, with part of this payment booked under sales in the fiscal year under review.

\*1 Estimate based on "IMS World Review Preview (Dec 2011 MAT)," reprinted with permission of 2012 IMS Health©, all rights reserved.

## Anti-cancer and Cancer-supportive Care

Sales in Japan of the anti-cancer agent *TS-1* were affected by a decline in the number of gastric cancer patients. However, there was growth in new prescriptions for conditions such as lung cancer and colorectal cancer driven by evidence-based medicine approaches. Sales of the anti-cancer agent *UFT* and reduced folic acid formulation *Uzel* both declined as a result of competition.



On the other hand, sales of the newly released antiemetic agent *Aloxi* and the anti-cancer agent *Abraxane* grew steadily, taking advantage of their product characteristics. Overseas, sales of *TS-1 | Teysuno* started in Europe through an alliance with the Nordic Group BV. The anti-cancer agent *SPRYCEL*, which is being co-promoted in Japan, the U.S., and Europe with Bristol-Myers Squibb Company, registered solid sales growth on progress in securing approval as a first-line treatment for chronic myeloid leukemia in markets worldwide. However, the distributions received by the Company in line with sales declined slightly due to the persistently strong yen.

BUSULFEX, which is the only allogeneic hematopoietic stem cell pre-transplant regimen approved by the U.S. Food and Drug Administration (FDA), is currently sold in over 50 countries, and has now become established as the standard drug as a conditioning agent administered prior to bone marrow transplants in place of total body radiation.

## **Cardiovascular System**

In this area, more and more medical professionals are becoming aware of the first-in-class drug *SAMSCA*, which is drawing attention for the new value it brings and its method of use as a diuretic that results in the excretion of water only, without affecting the excretion of electrolytes. In the U.S., sales of *SAMSCA* were double the level of the

previous fiscal year. In Japan, one year has passed since *SAMSCA*'s launch, and it is increasingly being recognized as an important treatment option for edema in heart failure, and an additional indication was filed for hepatic edema.

Sales of the antiplatelet agent *Pletaal/Pletal* have been impacted by generics, but sales were stronger than the Company's estimate due to an increase in prescriptions for cerebral infarction sequelae following the switch to orally disintegrating tablets, which are easier to use as they can be taken without water.



#### Other Fields

In the gastrointestinal area, steps were taken to leverage the brand power of the anti-gastritis and anti-gastric ulcer agent *Mucosta* in an effort to counter the impact of generics. In the area of ophthalmology, *Mucosta ophthalmic suspension UD 2%*, in which *Mucosta* is applied as a treatment for dry eyes, was launched in January 2012 in Japan. This agent is the first dry eye treatment in Japan which has a mechanism that stabilizes the tear film and has been proven to improve the uncomfortable symptoms of dry eyes.





## Clinical Nutrition Business

The clinical nutrition business is carried out primarily by Otsuka Pharmaceutical Factory, whose business creed is to be the "best partner of patients and healthcare professionals in the field of clinical nutrition." The company has contributed to parenteral management of patients by developing a full lineup of products with outstanding quality to meet the needs of physicians, based on its advanced sterilization technology. These products include Japan's first plastic bottle pack and an aseptically prepared antibiotic kit. The company operates an intravenous solutions business in international markets as well as Japan, with production bases in seven other countries\*2, mainly in Asia.

In fiscal 2011, the high-calorie TPN solution *ELNEOPA* registered solid sales in Japan, mainly because of wider adoption by hospitals and an increase in prescriptions in response to promotion of the benefits of the trace elements in the product and the convenience of the quad-bag kit formulation that permits instantaneous one-push sterile compound preparation.

\*2 Including non-consolidated subsidiaries and affiliated companies accounted for by equity method

## Diagnostics Business

### Core products

Brand name	Category	Manufacture and marketing
UBIT	Diagnostic agent for H. pylori	Otsuka Pharmaceutical
Quick Navi-Flu	Influenza virus test kit	Otsuka Pharmaceutical
Uropaper III Eiken	Urinalysis test strip	Otsuka Pharmaceutical

The diagnostics business focuses on the development and sale of intracorporeal and extracorporeal diagnostic agents for clinical use and research-use reagents. In the field of infectious diseases, Otsuka Pharmaceutical's influenza virus test kit *Quick Navi-Flu*, an agent for in vitro diagnosis, have met significant demand and contributed to the growth of the diagnostics business.







## Medical Devices Business

#### Core product

Brand name	Category	Manufacture and marketing
Adacolumn	Apheresis device for leukocyte adsorption	JIMRO

In the medical devices business, JIMRO manufactures and markets *Adacolumn*, an apheresis device for leukocyte adsorption in intractable inflammatory bowel disease. *Adacolumn*, which is used in the treatment of inflammatory bowel disease, works mainly by removing granulocytes and monocytes from peripheral blood using extracorporeal circulation.

In February 2011, Otsuka Medical Devices Co., Ltd. was established with the aim of developing the medical devices business into one of the Otsuka Group's core businesses.



## The Otsuka Group's Challenges for Further Growth



Highlight 1

# Antipsychotic *ABILIFY*Surging Ahead on the World Stage











## ABILIFY is marketed in 60 countries and regions

Algeria Australia Austria Bahrain Belgium Brazil Bulgaria Canada Chile
China
Colombia
Cyprus
Czech Republic
Denmark
Egypt
Estonia

Finland France Germany Greece Hungary Iceland Indonesia Ireland

Italy
Japan
Jordan
Kuwait
Latvia
Lebanon
Lithuania
Luxembourg

Mexico Netherlands New Zealand Norway Oman Phillippines Poland Portugal

Puerto Rico Qatar Romania Russia Saudi Arabia Singapore Slovakia Slovenia South Africa South Korea Spain Sweden Switzerland

Taiwan Thailand

Turkev

UK USA Venezuela

UAE

ABILIFY is the world's first antipsychotic to exert partial agonist action on dopamine D2 receptors. Otsuka Pharmaceutical began research and development in the field of CNS in the 1970s and ABILIFY is the fruit of a quarter century of research. Launched in the U.S. in 2002, followed by expansion into Europe and Asia, ABILIFY is today used in the treatment of numerous patients in 60 countries and regions, including Japan.

In the treatment of schizophrenia and manic episodes of bipolar disorder, it is important to continue taking the drug over the long term. Since it is not likely to cause side effects such as drowsiness and weight gain, *ABILIFY* can be taken for a long time, helping patients suffering from mental illness reintegrate into society. Additionally, Otsuka Pharmaceutical is aiming to ensure that patients can continue treatment without loss of quality of life

(QOL) by providing several formulations, including oral solution, orally disintegrating (OD) tablets, and once-monthly intramuscular depot formulation.

In the U.S., the Company is promoting the expansion of *ABILIFY* in cooperation with Bristol-Myers Squibb. With 13 indications, including schizophrenia and major depression, the product has grown rapidly thus far as a treatment for mental disorders. Thanks to its safety profile, *ABILIFY* is even used for the treatment of schizophrenia, bipolar disorder and autism in

children, showing tremendous achievements.

In Europe, with the indication of bipolar disorder, and in Asia—such as China, South Korea, Indonesia, and Taiwan—the product has grown in a major way. In Japan, manic episodes of bipolar disorder were added as a new indication in January 2012, in addition to the already approved schizophrenia. In May, OD tablets that quickly dissolve in the mouth were launched to provide patients with a formulation that is easier to take.

# Embracing More Challenges in the CNS Field

On November 11, 2011, Otsuka Pharmaceutical entered into an alliance agreement with Danish company Lundbeck, a global leader in the field of CNS disorders, with the aim of accelerating growth in the CNS field. The agreement includes co-development and co-commercialization of aripiprazole intramuscular depot formulation and OPC-34712. At a time when many pharmaceutical companies have experienced challenges in bringing new CNS therapies to market, Otsuka Pharmaceutical and Lundbeck will take a different and—true to their entrepreneurial cultures—unconventional approach to delivering new treatment options. Both companies are committed to developing innovative drugs that benefit the mental health of patients and their families worldwide.

Aripiprazole depot injection is a sterile, lyophilized cake. The U.S. Food and Drug Administration (FDA) has accepted a new drug application for the product as a once-monthly injection with the indication of treatment for schizophrenia. Otsuka Pharmaceutical



and Lundbeck presented results from the Phase 3 trials evaluating the efficacy, safety, and tolerability of the product as a maintenance treatment for adults with schizophrenia. Trial results were presented at the American Psychiatric Association (APA) Annual Meeting held in May 2012.

Also in the CNS field, Otsuka Pharmaceutical has introduced *E Keppra*, an antiepileptic drug, to Japan through a co-promotion alliance with UCB Japan. The product received long-term prescription approval in October 2011 and is experiencing major growth. It is already used in 92 countries around the world.

## Research and Development Activities



er, Tokushima Research Institute (Otsuka Pharmaceutical)

First Institute of New Drug Discovery
Institute of Biomedical Innovation

Research and Development Center

Tokushima Research Center





Tsukuba Research Center (Taiho Pharmaceutical)

10th Research Center, Tokushima Research Institute (Otsuka Pharmaceutical)

## **Otsuka Group R&D Facilities**

Medical Chemistry Research Institute Technical Center

Microbiological Research Institute

Tokushima Research Institute

Formulation Research Institute

Tokushima

- ●···Otsuka Pharmaceutical ★···Otsuka Pharmaceutical Factory ▲···Taiho Pharmaceutical
- Basic Research Clinical Development

## Shiga — Fujii Memorial Research Institute

- Third Institute of New Drug Discovery R&D department of Diagnostic Division Hyogo
  - Ako Research InstituteSaitama
- **Tokyo** R&D department of Diagnostic Division
- \* Research and Development Center Clinical Development Department
- ▲ Clinical Research & Development Center

#### Osaka

- Headquarters of New Product Evaluation and Development
- Clinical Development Department,

  Division of Dermatologicals & Ophthalmologicals.





Otsuka Shanghai Research Institute



Fujii Memorial Research Institute (Otsuka Pharmaceutical)



Otsuka Maryland Medicinal Laboratories, Inc.

## Pipeline Information (as of June 30, 2012)

Code / Brand name	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Developm status
Central nervous syste	· ·m					
				Schizophrenia / Depot injection	US	Filed
DDC 14E07 (ADILIEV*)	arininga ala	Otsuka Dharmasautisal	Danamina partial agenist	Schizophrenia / Depot injection	EU, JP	Phase II
OPC-14597 (ABILIFY*)	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Adjunctive therapy for major depressive disorder / Oral	JP	Phase I
	1			Tourette's disorder / Once-weekly tablet	US	Phase I
				Epilepsy (partial onset seizures for pediatric patients) / Oral	JP	Filed
				Epilepsy (generalized onset seizures) / Oral	JP	Phase I
.059 (E KEPPRA*) levetiracetam	UCB	Anti-epileptic drug	Epilepsy (partial onset seizures) / injection	JP	Phase I	
				Epilepsy (partial onset seizures / mono therapy) / Oral	JP	Phase I
				Parkinson's disease / Patch	JP	Filed
PM-962 (NEUPRO*)	rotigotine	UCB	Dopamine agonist	Restless legs syndrome / Patch	JP	Filed
				Adjunctive therapy for major depressive disorder / Oral	US, EU	Phase
PC-34712		Otsuka Pharmaceutical	Dopamine partial agonist	Schizophrenia / Oral	JP, US, EU	Phase
71 C-347 12		Otsuka i Hallilaceuticai	Dopariirie partiai agonist	· · · · · ·		1
Austinean and cons				ADHD(Adults) / Oral	US	Phase
Inti-cancer and cance	er-supportive care		i	6.1:	LIC.	, pl
-1 S-1(Japan, Korea)	1			Gastric cancer / Oral	US	Phase I
EYSUNO*(EU)	tegafur, gimeracil,	Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Uterocervical cancer / Oral	JP, Asia	Phase
S-ONE*(Singapore) 愛斯万*(China)	oteracil potassium	Idilio Fildililaceutical	: Anti-cancer (Anti-metabolite)	Hepatocellular carcinoma / Oral	JP	Phase
ど射力 "(Cnina) を斯萬*(Taiwan)	1 1 1		1	Renal cell cancer / Oral	JP	Phase
CANIFE (TELLIFICATION)	andienal anesia kanadanesiala			NSCLC / Injection	JP	Filed
BI-007(Abraxane)	paclitaxel protein-bound particle for injectable suspension	Celgene	Anti-cancer (nanoparticle)	Gastric cancer / Injection	JP	Filed
VF	fentanyl citrate	Teva Pharmaceutical	Narcotic analgesic	Cancer pain / Buccal	JP	Phase
VF	; lentanyi citiate	ieva riidiiiiaceuticai	i Narcotic analyesic			1
TII CO		(6)	A-4: (NA-11	Hepatocellular carcinoma / Oral	JP, Asia	Phase
SU-68	orantinib	(Sugen)	Anti-cancer (Molecular targeted drug)	Gastric cancer / Oral	JP	Phase
A.T. 1514	1	CALE	C II II (TUC CDD)	Colorectal cancer / Oral	Asia	Phase
ATIVEX*	nabiximols	GW Pharmaceuticals	Cannabinoid (THC, CBD)	Cancer pain / Oral spray	US	Phase
AS-102		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Colorectal cancer / Oral	JP, US, EU	Phase
TS102	elpamotide	OncoTherapy Science	Therapeutic cancer vaccine	Biliary tract cancer / Injection	JP	Phase
CV-101		OncoTherapy Science	Therapeutic cancer vaccine	Pancreatic cancer / Injection	JP	Phase
PRYCEL	dasatinib	BMS	Anti-cancer	Pancreatic cancer / Oral	US, EU	Phase
AS-106		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Solid tumors / Injection	US	Phase I
T-743	trabectedin	PharmaMar	Anti-cancer	Malignant soft tissue sarcoma / Injection	JP	Phase
PB-31121		Otsuka Pharmaceutical	Anti-cancer	Anti-cancer / Oral	JP, Asia	Phase
PB-51602		Otsuka Pharmaceutical	Anti-cancer	Anti-cancer / Oral	US, JP, Asia	Phase
PB-111001		Otsuka Pharmaceutical	Anti-cancer	Prostatic cancer / Oral	JP	Phase
CV-105		OncoTherapy Science	Therapeutic cancer vaccine	Pancreatic cancer / Injection	JP	Phase
AS-114		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Solid tumors / Oral	JP, US, EU	Phase
AS-115		Taiho Pharmaceutical	Anti-cancer (Molecular targeted drug)	Solid tumors / Oral	JP	Phase
	1			Secondary prevention of elderly acute		
CV-501		Otsuka Pharmaceutical	WT1 targeted cancer vaccine	myeloid leukemia / Injection	JP	Phase
Cardiovascular						
DC 41061 (CAMCCA*)	talvantan	Otsuka Pharmasautisal	Vasopressin V₂-receptor antagonist	Autosomal dominant polycystic kidney disease / Oral	US, EU, JP	Phase II -
PC-41061 (SAMSCA*)	tolvaptan	Otsuka Pharmaceutical	vasopiessiii v2-ieceptoi antagonist	Hepatic edema / Oral	JP, Asia	Phase
PC-108459		Otsuka Pharmaceutical		Paroxysmal and persistent atrial fibrillation / Injection	JP, US	Phase
Other areas						
tilei alcas						Phase
		Ottoriles Blassess souties!	Mucin-production	Dry eyes / Eye drops	US	, 111030
PC-12759E (Mucosta	rebamipide	Otsuka Pharmaceutical	Mucin-production enhancing agent	Dry eyes / Eye drops Keratoconjunctival disorder	US JP	i
PC-12759E (Mucosta )phthalmic Suspension)			enhancing agent	Keratoconjunctival disorder Peritonitis, intraabdominal abscess,	JP	Phase
PC-12759E (Mucosta )phthalmic Suspension)	rebamipide piperacillin sodium, tazobactam sodium	Otsuka Pharmaceutical  Taiho Pharmaceutical	enhancing agent $eta$ -lactamase inhibitor-	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection	JP JP	Phase Filed
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*)	piperacillin sodium, tazobactam sodium	Taiho Pharmaceutical	enhancing agent $oldsymbol{eta}$ -lactamase inhibitorantibiotic agent	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection	JP JP JP	Phase Filed Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*)	piperacillin sodium,		enhancing agent $eta$ -lactamase inhibitor-	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral	JP JP JP JP	Phase Filed Phase Filed
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*)	piperacillin sodium, tazobactam sodium saxagliptin	Taiho Pharmaceutical Bristol-Myers Squibb	enhancing agent $\mathcal{B}$ -lactamase inhibitorantibiotic agent DPP-IV inhibitor	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection	JP JP JP	Phase Filed Phase Filed
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*)	piperacillin sodium, tazobactam sodium	Taiho Pharmaceutical	enhancing agent $oldsymbol{eta}$ -lactamase inhibitorantibiotic agent	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral	JP JP JP JP, Asia JP, US, Asia	Phase Filec Phase Filec Phase II Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535	piperacillin sodium, tazobactam sodium saxagliptin	Taiho Pharmaceutical Bristol-Myers Squibb	enhancing agent $\mathcal{B}$ -lactamase inhibitorantibiotic agent DPP-IV inhibitor	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral	JP JP JP JP, Asia JP, US, Asia EU	Phase Filed Phase Filed Phase II Phase Filed
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535	piperacillin sodium, tazobactam sodium saxagliptin tetomilast	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical	enhancing agent  \$\mathcal{B}\text{-lactamase inhibitor-} antibiotic agent}  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU	Phase Filed Phase Filed Phase II Phase Filed Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PPA-6566	piperacillin sodium, tazobactam sodium saxagliptin tetomilast	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical	enhancing agent  \$\mathcal{B}\$-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU US	Phase Filed Phase Filed Phase Filed Phase Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PPA-6566	piperacillin sodium, tazobactam sodium saxagliptin tetomilast	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical	enhancing agent  \$\mathcal{B}\$-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU	Phase Filed Phase Filed Phase Filed Phase Phase
PPC-12759E (Mucosta Ophthalmic Suspension) P-18 (ZOSYN*) PPC-262 (ONGLYZA*) PPC-6535 PPC-67683 PPA-6566 ACU-4429	piperacillin sodium, tazobactam sodium saxagliptin tetomilast	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical	enhancing agent  B-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator  Recombinant peptide for immunotherapy	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU US	Phase Filec Phase II Phase II Phase Filec Phase Phase Phase Phase II Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PA-6566 CU-4429 AC-201	piperacillin sodium, tazobactam sodium saxagliptin tetomilast delamanid	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical Acucela Meiji	enhancing agent  B-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator  Recombinant peptide for immunotherapy of Japanese cedar pollinosis	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops Dry AMD / Oral Cedar pollen allergy / Injection	JP JP JP, Asia JP, US, Asia EU JP, US, EU US US JP	Phase Filec Phase II Phase II Phase Filec Phase Filec Phase I Phase
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PA-6566 CU-4429 AC-201 PB-2045G	piperacillin sodium, tazobactam sodium saxagliptin tetomilast	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical Acucela	enhancing agent  B-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator  Recombinant peptide for immunotherapy of Japanese cedar pollinosis	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops Dry AMD / Oral	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU US US	Phase Filed Phase II Phase II Phase Filed Phase Filed Phase Phase I
PC-12759E (Mucosta ophthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PA-6566 CU-4429 AC-201 PB-2045G Diagnostics	piperacillin sodium, tazobactam sodium saxagliptin tetomilast delamanid	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical Acucela Meiji Otsuka Pharmaceutical Factory	enhancing agent  \$\mathcal{B}\$-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator  Recombinant peptide for immunotherapy of Japanese cedar pollinosis  Anti-septics	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops Dry AMD / Oral Cedar pollen allergy / Injection Patient preoperative preparation / Topical	JP JP JP JP, Asia JP, US, Asia EU JP, US, EU US US JP	Phase Filed Phase Filed Phase II Phase Filed Phase I Phase Phase I Phase I
PC-12759E (Mucosta phthalmic Suspension) P-18 (ZOSYN*) PC-262 (ONGLYZA*) PC-6535 PC-67683 PA-6566 CU-4429 AC-201 PB-2045G	piperacillin sodium, tazobactam sodium saxagliptin tetomilast delamanid	Taiho Pharmaceutical Bristol-Myers Squibb Otsuka Pharmaceutical Otsuka Pharmaceutical Otsuka Pharmaceutical Acucela Meiji	enhancing agent  B-lactamase inhibitor- antibiotic agent  DPP-IV inhibitor  Anti-inflammatory agent  Anti-tuberculosis agent  Adenosine A2a receptor agonist  Visual cycle modulator  Recombinant peptide for immunotherapy of Japanese cedar pollinosis	Keratoconjunctival disorder Peritonitis, intraabdominal abscess, cholecystitis, cholangitis / Injection Febrile neutropenia / Injection Type2 diabetes mellitus / Oral Crohn's disease/Oral COPD / Oral Multidrug-resistant tuberculosis / Oral Glaucoma / Eye Drops Dry AMD / Oral Cedar pollen allergy / Injection	JP JP JP, Asia JP, US, Asia EU JP, US, EU US US JP	Phase Filec Phase II Phase II Phase Filec Phase Filec Phase I Phase

Note 1: In general, Otsuka discloses compounds that are in Phase II or later stage of development, although some compounds in Phase I are included in the above table. Note 2: Product names with asterisk '\*' are the names used outside Japan.

Note 3: \*\* Preparation for additional study.

<sup>&</sup>lt; Events after June 30, 2012 >
\*OPC-12759E (rebamipide): Dry eyes / Eye drops (US), Phase III→III, July 2012 \*OPC-41061 (tolvaptan): Hepatic edema (JP), Phase III→Filed, July 2012.

## Research and Development Updates

## **Central Nervous System**

In January 2012, the antipsychotic *ABILIFY* obtained approval in Japan for the additional indication of ameliorating the manic symptoms associated with bipolar disorder. Development activities are also being conducted in Japan for an additional indication of adjunctive therapy in major depressive disorder.

A new drug application for the aripiprazole intramuscular depot formulation for the treatment of schizophrenia was accepted for review by the FDA. In Japan and Europe, the drug is currently in Phase 3 stage for schizophrenia. In Europe and the U.S., the drug's Phase 3 trials for bipolar disorder are expected to begin in fiscal 2012.

Developed as a next-generation antipsychotic, OPC-34712 has advanced to Phase 3 clinical trials for major depressive disorder and schizophrenia in Europe and the U.S. Phase 2 trials are also being carried out in the U.S. for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults. In Japan, Phase 3 trials for schizophrenia are now under way.

Phase 3 trials for *E Keppra*, an antiepileptic drug promoted in collaboration with UCB Japan since September 2010, began in Japan as an injection and oral monotherapy for epileptic partial seizures. In June 2012, applications were filed for the additional indication of epileptic partial seizures in children using oral tablets and for the additional formulation of oral dry syrup.

In Japan, applications for rotigotine patch, which has been developed as a dopamine agonist transdermal patch preparation, were filed in December 2011 for the treatment of two disorders: Parkinson's disease and restless legs syndrome.

## Anti-cancer and Cancersupportive Care

A co-development and co-commercialization agreement in Europe was concluded with Nordic

BV of the Netherlands in July 2011 concerning the anti-cancer drug *TS-1*. In March 2012, sales of the product in Europe under the name *Teysuno* were launched, starting in the four Nordic countries of Sweden, Denmark, Norway and Finland. *TS-1* is currently sold in 15 countries worldwide (as of July 31, 2012). New evidence relating to the effectiveness of *TS-1* was produced by Phase 3 trials in patients with non-small-cell lung cancer and was presented at a meeting of the American Society of Clinical Oncology in June 2012. The study showed that a combination therapy of *TS-1* and cisplatin may be an option for future lung cancer treatment, along with the standard therapy of docetaxel and cisplatin.

SPRYCEL is an anti-cancer agent discovered by Bristol-Myers Squibb Company and is being codeveloped and co-promoted globally with the Company. An additional indication for SPRYCEL as a first-line treatment for chronic myeloid leukemia in adults was approved in Japan in June 2011, following same approval in the U.S.

In June 2012, global Phase 3 trials were begun for the new anti-cancer drug TAS-102, which is intended for advanced or recurrent colorectal cancer that does not respond to standard treatment. The results of Phase 2 trials for TAS-102 were presented at the 9th Annual Meeting of the Japanese Society of Medical Oncology in July 2011 and the European Multidisciplinary Cancer Congress in September 2011.

Applications were filed in February 2012 for approval of the additional indications of gastric cancer and non-small-cell lung cancer for the anti-cancer drug *Abraxane*.

OCV-105 is a cancer vaccine being developed in collaboration with OncoTherapy Science, Inc. Phase 1 trials for the treatment of pancreatic cancer have been initiated. Phase 1 trials were also begun for OCV-501, a WT1-targeted cancer vaccine. The trials are for the prevention of

recurrence of acute myeloid leukemia in elderly patients.

In the U.S., *SATIVEX* advanced to Phase 3 trials for the treatment of cancer pain.

## Cardiovascular System

Last year, SAMSCA, a new diuretic drug capable of selectively excreting only excess water without affecting the excretion of electrolytes, went on sale in Canada, China, and Taiwan and was approved in Hong Kong, South Korea, and Indonesia as a treatment for hyponatremia. In July 2012, an application was made in Japan for SAMSCA for the indication of hepatic edema.

Phase 1 trials have been initiated in Japan and the U.S. for OPC-108459, a treatment for paroxysmal and persistent atrial fibrillation.

## **Other Fields**

#### [Tuberculosis]

For over 30 years, Otsuka Pharmaceutical has been engaged in tuberculosis research and development as one of its most important projects. Currently, the anti-tuberculosis drug OPC-67683 (delamanid) is undergoing global Phase 3 trial for the treatment of multidrug-resistant tuberculosis. In December 2011, a new drug application was filed in Europe for this treatment. In June 2012, the late Phase 2 trial results on the safety and efficacy of OPC-67683 were published in *The New England Journal of Medicine*.

#### [Ophthalmology]

In January 2012, sales of *Mucosta ophthalmic* suspension UD 2% commenced in Japan. Used for the treatment of dry eyes, this product is based on the antigastritis and antigastric ulcer agent *Mucosta* (rebamipide). Overseas, in collaboration with Acucela Inc., development progressed for OPA-6566 for glaucoma, rebamipide ophthalmic suspension for dry eyes, and ACU-4429 for dry

age-related macular degeneration. In July 2012, Phase 3 trials were begun in the U.S. for rebamipide ophthalmic suspension.

#### **Clinical Nutrition**

In the clinical nutrition area, the electrolyte correction solution *Sodium Phosphate*Correction Solution 0.5 mmol/mL was launched in Japan in April 2011.

#### **Diagnostics**

In the diagnostics area, the WT1 mRNA assay kit *Otsuka*, which is already included in National Health Insurance (NHI) coverage and widely used as a monitoring marker for minimal residual disease in acute myeloid leukemia, was additionally approved for NHI coverage for myelodysplastic syndrome in August 2011.

RAPIRUN S. pneumoniae HS (otitis media, sinusitis), an in-vitro diagnostic kit for streptococcus pneumoniae, was launched in December 2011. The H. influenzae ELISA kit Otsuka was also approved as a diagnostic aid for H. influenzae infection.



## The Otsuka Group's Challenges for Further Growth



## Pursuing Real Needs of Cancer Patients— Taiho Pharmaceutical's SurvivorSHIP Initiatives

Making the research and development of anti-cancer agents a major part of its business for half a century, Taiho Pharmaceutical has been creating Japan's foremost anti-cancer drugs. As a leading company in cancer treatment, Taiho puts a great deal of effort into helping people who have experienced cancer overcome the challenges they face in life, together with their families, healthcare providers, and other cancer survivors—i.e., SurvivorSHIP.

# Making Taiho Pharmaceutical's Wealth of Experience Available to Cancer Patients and Their Families

Nowadays it is common to hear the term "cancer survivor." Taiho Pharmaceutical takes a broader view of SurvivorSHIP —offering support that encompasses the entire environment surrounding cancer survivors and their families—and is undertaking various support initiatives.

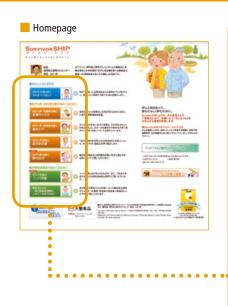
In one initiative, the company has been conducting joint research with the Shizuoka Cancer Center on how best to provide information to patients undergoing anti-cancer treatment as well as to their families. As an outcome of the research, the company launched the SurvivorSHIP.jp website in Japanese in 2007. At present, the website has seven categories of content that introduce schemes and hints for resolving worries faced by patients and their families during

chemotherapy or radiation therapy, providing support so that patients and the people around them can live comfortably and face cancer together.

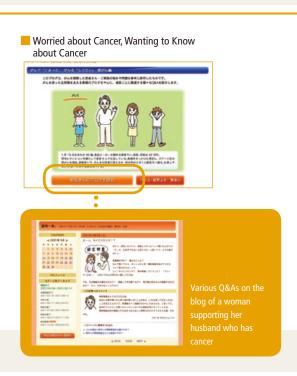
## Responding to Common Concerns with Comprehensive Content

## Sharing the Voices of Patients and Their Families

One content section that was published at the time the website opened is Meals with Chemotherapy and Radiation Therapy. This section is a complete online version of the book by the same title. It features ingenious ways of reducing the various side effects of chemotherapy and radiation therapy, describes countermeasures to take when side effects appear, and features patients' worries and advice from doctors,







nurses, and nutritionists. The site also includes 176 recipes for meals that are appropriate for people with certain conditions or for whom special considerations are required. The same information has also been developed into an Apple iPhone/ iPad application, which generated a lot of feedback from many quarters when it was released.

Another section of the website, entitled Worried about Cancer, Wanting to Know about Cancer—the Stomach Cancer Version, provides Q&As on the blog of a woman whose husband has cancer. The objective is to enable patients and their families to resolve the numerous worries they face from the time of cancer diagnosis. There are a total of 100 Q&As covering such matters as the worries and burdens of medical care, day-to-day life and physiological drives, relationships with healthcare providers and family members, employment and financial problems, and mental issues such as anxiety.

A section entitled Hair Loss with Chemotherapy and Radiation Therapy focuses on this common occurrence in cancer treatment. The section includes videos on how to put on and care for a wig and different ways of wearing a scarf, so that patients can put them into practice. It also describes makeup techniques for eyelashes and eyebrows.

Another section is Lymphedema after Cancer Surgery. This section highlights lymphedema, which previously was not often discussed, since it is an aftereffect of surgery, despite the fact that it is an issue that worries many patients. Using

writing, illustrations, and audiovisual content, this section provides clear explanations of what lymphedema is and how patients can care for it on their own.

The Chemotherapy and Eye Symptoms section focuses on anti-cancer drugs with a high likelihood of causing side effects in the eyes and describes those side effects.

Additionally the website includes audiovisual content that explains chemotherapy and ways of dealing with its side effects, as well as videos that describe problems following gastric resection and ways to deal with them.

## Providing Better Information to Improve Patients' Quality of Life

Cancer treatment is not something faced by patients alone; it is a joint effort that also includes healthcare providers and family members. This is the idea behind SurvivorSHIP, and it is thought that patients and their families mutually supporting each other is what will lead to the realization of true health. Going forward, Taiho Pharmaceutical will continue to provide information from the viewpoint of patients and their families, not only to enhance treatment of disease but also to improve the quality of life of patients who have to undergo long treatments.



Chemotherapy and How to Deal with Its Side Effects



Hair Loss with Chemotherapy and Radiation Therapy



Lymphedema after Cancer Surgery



\*This website is Japanese only

## Nutraceutical Segment

## **Overview of Nutraceutical Segment**

The Otsuka Group's Nutraceutical Business focuses on functional beverages and foods that help maintain and promote day-to-day well-being.



### **Otsuka Pharmaceutical**

Otsuka Pharmaceutical leverages the know-how it has cultivated in pharmaceutical business to develop products to support and maintain health in people's daily lives.

The company aims to contribute to the maintenance and improvement of health through the creation of new product categories by developing innovative products such as the electrolyte drink *Pocari Sweat*, based on the concept of "a sweat drink," and the balanced nutritional food *Calorie Mate*, which makes it easy to access the five major nutrients.

In recent years, the company developed the fruit and soy bar *SOYJOY* and the carbonated soy beverage *SOYSH*, based on the belief that soybeans, which are an integral part of Japanese food culture, could provide a solution to global health and environmental issues.

In April 2012, the healthy soy snack *SoyCarat* was launched. Otsuka is giving the world new ways to enjoy soy, with all of its abundant nutrition.

## **Otsuka Pharmaceutical Factory**

Otsuka Pharmaceutical Factory is engaged in research and development mainly of medical food and foods for special dietary use that can be used in medical facilities, nursing homes, or at home. OS-1, a food for special dietary use by the ill, is put to use in many situations as an oral rehydration supplement that effectively replenishes water and electrolytes in patients suffering from dehydration. ENGELEAD, a food for special dietary use by people who have difficulty chewing and swallowing, helps the nutritional management of these patients. The HINE series of high-density liquid diet products is useful in the nutritional management of people who cannot take meals.

#### Taiho Pharmaceutical

Taiho Pharmaceutical is actively engaged in developing OTC products that are used for a variety of health conditions and symptoms, with a unique lineup of products with proven effectiveness and special attributes. The vitamin health drink *Tiovita Drink*, the crude drug gastrointestinal remedy *Solmack*, and *Harncare*, a crude drug for mild incontinence and urinary frequency, are all well-known brands. *Henseki*, which is effective for adipositas, has potential for growth.

## Sales Activities

Pocari Sweat, an electrolyte supplement drink, is sold in 17 markets, mainly in Asia. In markets outside Japan, sales volume grew by more than 20% year on year, as consumers responded to ongoing promotion activities emphasizing product value. Sales of Pocari Sweat were particularly strong in Indonesia, where they reached a new record high. In the Japanese market, promotion efforts in the lead-up to summer focused on the prevention of heat stroke, using the phrase "Every 100ml contains 49mg of sodium," while marketing from the autumn emphasized the importance of replacing fluids as part of a daily routine. There was an increase in sales of the 900ml bottle, which was launched to meet more diverse consumer needs. Although sales volume in Japan was lower than the level in the previous fiscal year, when the severe summer heat had a favorable impact on sales, sales volume was generally in line with targets.

The Group focused on promoting the value of the fruit soy bar SOYJOY, which is sold in 11 markets around the world and packed with the wholesome nutrition of soy. For the soy soda beverage SOYSH, the Group worked on attracting customers by implementing a consumer awareness campaign about the health benefits of soy, targeting a total of roughly five million people throughout the country. In April 2012, the Group launched SoyCarat, a nutritional soy snack that rattles when shaken, as the third Soylution product.

In the U.S., Nature Made, which is supplied by the subsidiary Pharmavite LLC, is now stocked by all Wal-Mart stores in the U.S. and in addition, registered strong exports sales to the Middle East, driving healthy sales. In Japan, steps were taken to attract customers by using high credibility as a brand, emphasizing the status of Nature Made as the No. 1\*1 pharmacistrecommended supplement in the U.S. for five consecutive years, and promoting Super Multi

Vitamins & Minerals and Super Fish Oil, "one tablet a day" supplements launched in June 2011.

Sales at Nutrition & Santé SAS of France, which is a subsidiary that operates in more than 40 countries, mainly in Europe, were driven by organic food products and diet food products. In Japan, nationwide sales of the nutrition and health food brand Gerblé began in October 2011. A decision was also taken to start nationwide sales of *Gerlinea*, the leading\*2 calorie control brand in the French diet food market. The addition of new items is set to strengthen the product lineup, contributing to the penetration of the brand.

Sales of the carbonated nutritional drink Oronamin C grew as its customer base expanded, particularly among young consumers. This was a result of the partnership with Ito En Limited in the vending machine business, which started in April 2011, in addition to continued efforts to acquire customers. In May 2011, Oronamin C's presence in the market was further enhanced when it became the first small-volume bottled vitamin drink to register cumulative sales of over 30 billion units in Japan.

Sales of the balanced nutrition food Calorie Mate were below the level of the previous fiscal year, but it remains a leading brand in the nutritional food category as a readily available source of the five main nutrients.

In the cosmedics area, where the Company is promoting the concept of "healthy skin," UL-OS Scalp Shampoo (medicated) was launched in September 2011 in the UL-OS men's skincare brand. The UL-OS range now contains a comprehensive lineup of products for all areas of men's skincare. The brand was also launched in South Korea in March 2012, marking the first move overseas by the cosmedics business.

The vitamin health drink Tiovita Drink registered steady growth in sales volume due to an aggressive marketing strategy.

<sup>\*1</sup> *Pharmacy Times*, 2011 \*2 IRI, July 2009 (PDM volume CC P7)

## **Nutraceutical Segment Topics**

## Healthy Soy Snack *SoyCarat* Is the Third Product Launched in the Soylution Lineup

Introducing a new way to consume soybeans worldwide under the theme of "Soylution," Otsuka Pharmaceutical broke the conventional rule of snack foods and came out with something healthy: SoyCarat, a snack made mainly with whole soybeans, including okara (the fiber and protein extracted when making soy milk and tofu). The product was launched in Japan on April 11, 2012.

While a single pack contains the equivalent of about 50 soybeans, *SoyCarat* has a mild flavor that softens the characteristic taste of soy. With a fun rattling sound made when shaken and low calories from a non-fry cooking method, the product provides a delicious and fun way to get the nutrition of soy.

SoyCarat is the third product in the Soylution lineup, following the fruit soy bar SOYJOY sold in 11 countries and regions around the world and the sparkling soy beverage SOYSH sold in Japan. Otsuka Pharmaceutical intends to spread the value of soy through SoyCarat with global markets in its sights.



## Launch of *UL-OS* Medicated Scalp Shampoo Provides Intensive Care, Starting from the Scalp



On September 13, 2011, Otsuka Pharmaceutical launched a new addition to its *UL-OS* skin care brand for middle-aged men: *UL-OS* Medicated Scalp Shampoo, which supports the health of the scalp as well as the hair.

Otsuka Pharmaceutical has continued its skin research for over 20 years based on the concept that "healthy skin is beautiful skin." The *UL-OS* Medicated Scalp Shampoo was developed with the aim of providing care for men's scalp and hair. The addition of this product brings the *UL-OS* lineup to 14 items in seven categories, making it a brand that provides total body care, from head to toes. Going forward, the company will continue offering ways for men to keep their skin healthy with the *UL-OS* brand.

UL-OS Brand Launches in South Korea—the First Market Outside Japan—Three and a Half Years after Its Initial Debut On March 5, 2012, Otsuka Pharmaceutical introduced its *UL-OS* skin care brand for men in South Korea through its subsidiary Korea Otsuka Pharmaceutical. The company launched seven items in five categories—Skin Lotion, Skin Milk, Skin Cream, Medicated Skin Wash, and Refresh Sheet (medicated cosmetics)—and plans to increase the lineup in the future. The company will promote the value of the *UL-OS* brand in the South Korean market as it looks to establish a solid presence in the country, where men are becoming more conscious of their skin care needs.

## **Pocari Sweat** Making Great Strides around the World

Originating in Japan, Otsuka Pharmaceutical's *Pocari Sweat* is a global product sold in 17 countries and regions worldwide, including Vietnam, where *Pocari Sweat* was launched for the first time in 2012. Today, sales of *Pocari Sweat* outside Japan are growing to the point where they will overtake the number of bottles sold in Japan. Furthermore, since the product's development as a beverage for quickly replenishing fluids and electrolytes lost through perspiration, the company has continued research for the past 30 years in hopes of finding further evidence. Since June 2012, Major League baseball

player Yu Darvish has appeared in Japanese commercials for *Pocari Sweat*, which continues to make constant progress as a world-class beverage.



## Solid Sales of *Tiovita Drink* on the Back of Improved In-store Promotion

Taiho Pharmaceutical's multivitamin health tonic, *Tiovita Drink* (designated a quasi-drug), again recorded solid sales. While the health drink market faced an uphill battle in fiscal 2011, the number of bottles of *Tiovita Drink* sold reached a new record of 250 million. A larger display size and improved in-store promotion—achieved through a Display POP Contest conducted since 2010, in which more than 10,000 retailers participated—contributed greatly to the growth in sales volume. Going forward, Taiho Pharmaceutical will keep on striving to develop an even larger base of loyal customers

for Tiovita Drink.

## Main Nutraceutical Products



#### Pocari Sweat (1980)

Health drink swiftly replenishing fluids and ions (electrolytes) lost through perspiration. An optimal ion balance aids quick absorption by the body, making *Pocari Sweat* the ideal rehydration drink for use during and after sports activities or after taking a hot bath.



#### **SOYJOY** (2006)

Novel nutrition bar made using only soybean dough (wheat-free) with a generous amount of dried fruit. Consumers can enjoy the nutritional elements of soybeans including soy protein and soy isoflavones in a smart and tasty way.



#### Nature Made (1993)

The number one brand in the U.S.\* for vitamins, minerals and supplements essential for maintaining health, *Nature Made* contains no artificial colors, flavors or preservatives.

\*2010 Nielsen data: Share of sales in the distribution market in supermarkets, drug stores, mass retailers, and membership stores



#### Tiovita Drink (1964)

This vitamin health drink contains vitamins B1, B2, B6 and niacinamide in addition to inositol, taurine, the digestive aid carnitine chloride, and anhydrous caffeine as a pick-me-up. In addition to *Tiovita Drink* (designated a quasi-drug), the lineup also includes *Tiovita Gold*, a revitalizing OTC drug.



#### Oronamin C Drink (1965)

Carbonated nutritional drink containing Vitamin C and other vitamins. Only 120ml in size, *Oronamin C* provides a refreshing burst of energy.



#### SoyCarat (2012)

SoyCarat is a snack made with whole soybeans as the main ingredient. One bag contains the equivalent of about 50 soybeans. With a fun rattling sound made when shaken, SoyCarat provides a fun way to get the nutrition of soy. Since SoyCarat is not fried, a single pack contains only 123 calories. It is a snack that can be enjoyed by everyone, from children to adults.



#### **UL-OS** (2008)

A face and body skin care brand targeting middle-aged men based on the cosmedics concept of healthy skin support. Formulated with moisturizing ingredient AMP\*, application of *UL-OS* moisturize the skin and leads to healthy skin.

\*Adenosine monophosphate



#### **Oronine H Ointment** (1953)

Known for over half a century as an effective medication for treating various skin conditions, *Oronine H Ointment* was the first product to make the Otsuka name widely recognized.



#### Calorie Mate (1983)

Balanced nutritional bar containing all five major nutrients (protein, fat, carbohydrates, vitamins, minerals). Ideal as a nutritional supplement when under time pressure or when it is not possible to have a meal.



#### **SOYSH** (2010)

A beverage that creates a new category combining soy and carbon. Each 100 ml bottle contains the equivalent of about 21 large soybeans (grown in Japan), providing the full nutrition of soy contained in soy solids. SOYSH can be enjoyed without the distinctive aftertaste of soy thanks to the refreshing quality provided by carbonation.



#### Gerblé (2010)

A French health and nutrition food with a commitment to nutrition and fine ingredients, including wheat germ and fruits. Created in 1928, *Gerblé* has continued to be loved by the French, who are particular about flavor and ingredients, and enjoy well balanced meals: It is the top-selling brand in the French nutrition and health food market.



#### **OS-1** (2005)

An oral rehydration supplement formulated with an optimal balance of glucose and electrolytes. A medical food to supply and maintain water and electrolyte levels in patients suffering from mild to moderate dehydration, OS-7 is used to treat dehydration resulting from conditions including diarrhea, vomiting and fever caused by infectious enteritis or the common cold, insufficient oral intake of fluids among the elderly, or excessive perspiration.

## The Otsuka Group's Challenges for Further Growth



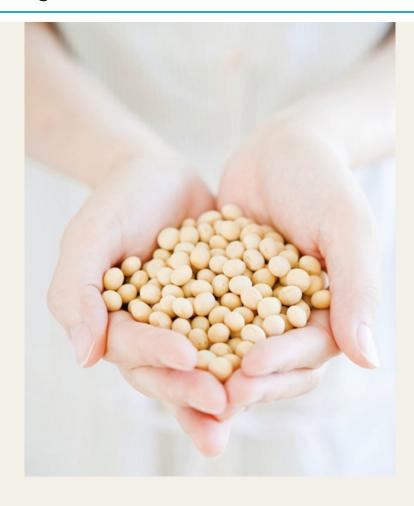
# Soylution

## Third Product in Soylution Lineup Launched: SoyCarat

Based on the Soylution concept—that soybeans can provide a solution to human health and environmental problems—Otsuka Pharmaceutical has been developing new soy products that offer delicious ways for people worldwide to conveniently benefit from whole soy nutrition.

After launching *SOYJOY*, the fruit soy bar, our two research institutes in Tokushima are concentrating on the development of soy foods, continuing the pursuit of forms and flavors acceptable to people around the world. The soy soda beverage *SOYSH*, launched in 2010, was developed at the First Research Institute of New Functional Products Development. *SoyCarat*, launched in April 2012, was developed at the Second Research Institute of New Functional Products Development.





## Soy and Otsuka's Soylution

Soy is one of Japan's traditional foods. Nowadays, researchers around the world are taking notice of soy's high nutritional value and possibilities. Professor Yukio Yamori, director of the Institute for World Health Development at Mukogawa Women's University, has studied eating habits and longevity worldwide for 30 years. In the WHO-CARDIAC Study, an international joint research study on cardiovascular disease and nutrition conducted in cooperation with WHO, Professor Yamori focused on the various funcions of soy. He has suggested, "The reason why the Japanese have the world's longest life expectancy is deeply related to the intake of soy in the diet. Soy will save the world." Sympathizing with Professor Yamori's WHO-CARDIAC Study, Otsuka Pharmaceutical employees have been joining his study as volunteers since 1985.



## Japan—the country with one of the world's highest longevity rates and the country where people consume the greatest amount of soy.

The Japanese, who have one of the highest life expectancies in the world, consume the greatest amount of soy, at 8.19 kg annually per person.\* Most Japanese bean consumption comes from processed soy products (e.g., tofu, fried tofu, and natto). In recent years, however, soy consumption by people aged 40 and younger has tended to be below the average due to the habit of skipping breakfast and to the Westernization of diets.\*

No more than 6 percent\*<sup>3</sup> of soybeans grown around the world are eaten directly by people. The U.S. is the world's largest producer of soybeans, but the annual U.S. consumption of soy products is about 40 grams\*<sup>4</sup> per person. This is less than the amount eaten by the average Japanese in a single day. The fact is that most soybeans are used as feed for livestock. It is said that it takes 10 kg of grains such as soy to produce 1 kg of beef, which is one source of protein. There is also data stating that it takes 1/50th the amount of water and 1/20th the amount of energy needed to produce soy as it does to produce the same amount of beef.\*<sup>5</sup> With the world population

expected to top nine billion in the near future, if people ate more soy directly, it could lead to the resolution of various health and environmental problems around the world.

- \*1 FAOSTAT food supply data, Food and Agriculture Organization of the United
- \*2 National Health and Nutrition Examination Survey 2010, Ministry of Health, Labour and Welfare of Japan
- \*3 U.S. Department of Agriculture
- \*/ [/
- \*5 Professor David Pimentel, Cornell University, U.S.A.

## Offering the World New Ways to Enjoy Soy

Based on its Soylution concept, Otsuka Pharmaceutical is offering the world new ways to consume whole soy, especially for people unaccustomed to eating it.

The first product in the Soylution lineup was the fruit soy bar *SOYJOY*, which was launched in Japan, the U.S., and China in 2006 and is now sold in 11 countries and regions around the world. *SOYJOY* also came in flavors suited to the cultures and eating habits of different countries, introducing pineapple in the U.S. and jujube in China as original items for those countries.

Otsuka Pharmaceutical has its sights set on the expansion of *SOYSH* and *SoyCarat* outside Japan in the future.



SOYSH

## Consumer Products Segment

## **Overview of Consumer Products Segment**

The Otsuka Group's consumer products segment provides a wide range of foods and beverages that are an integral part of consumers' lives, including: Bon Curry, which was the world's first commercially available food in a plastic pouch bag; Mannan Hikari, a food product that resembles rice but enables calorie control; CRYSTAL GEYSER, a brand of soft mineral water from California; and Sinvino Java Tea Straight, which has no added sugar.



#### **Otsuka Foods**

Otsuka Foods has offered the market new foods and beverages with novel ideas and reliable quality, under the motto "delicious, safe, reassuring, and healthy."

In the foods business, the company released *Bon Curry* in 1968. Since then, Otsuka Foods has introduced a number of industry-leading products, including *Micro Magic*, microwave-cooked french fries, and *Mannan Hikari*.

In the beverages business, Otsuka Foods offers a lineup of products that match consumers' tastes, including: *Sinvino Java Tea Straight*, which has become a longtime best-seller; *CRYSTAL GEYSER*, which is a soft mineral water bottled directly from a spring at the base of Mount Shasta; and *MATCH*, a carbonated vitamin drink.

In fiscal 2012, Otsuka Foods launched a white-tea version of *Sinvino Java Tea Straight*, in addition to the original red tea. Now customers have a new way to enjoy drinks according to the cuisine and atmosphere, matching the full-bodied flavor of the red to rich foods and the mild taste of the white to delicate dishes.

## Other Segment

## **Overview of Other Segment**

The Otsuka Group operates a range of businesses in areas that include chemicals, transportation and warehousing, and electronic equipment.



#### **Chemicals**

In the specialty chemical business, despite the tough operating environment caused by the Great East Japan Earthquake, the flooding in Thailand and the sovereign debt crisis in Europe, sales of the friction materials *TISMO* and *TERRACESS* recovered and grew from the second half of the fiscal year, supported by a recovery in the automotive field in the U.S. and solid market growth in China. Sales in the fine chemical business declined due to factors such as the impact from generics overseas on the antibiotic ingredient *YTR* and the impact of falling prices for the pharmaceutical intermediate *GCLE*.



Sinvino Java Tea Straight



MATCH



CRYSTAL GEYSER



VICHY Célestins



Ridge Wine



Mannan Hikari



Bon Curry Neo



Bon Curry Gold 21



My Size



Ginza Rouksant



Micro Mag

#### Sinvino Java Tea Straight

As a way of giving a symbolic shape to the concept of providing "more joy of choice to the joy of eating," the company held an event called Play Table in the Sky in 2012. At the first such event in Japan, a dining table was suspended 40 meters above the ground by a giant crane, providing an opportunity to enjoy *Sinvino Java Tea Straight* with food in an out-of-the-ordinary space.

Going forward, the company will strive to expand the market for *Sinvino Java Tea Straight*, not as a favorite beverage for teatime, but as an accompaniment to meals that will add sparkle to the dining table.

#### Mannan Hikari

Mannan Hikari enables people to control their calorie intake comfortably with their daily meals, while also getting dietary fiber. The product has been helping consumers with their diet since its launch in 2001 for both the commercial and industrial markets. Together with university students aspiring to be national registered dietitians, the company co-developed boxed lunches and rice balls made with Mannan Hikari, which attracted public attention.

Aiming to enter more new markets in the future, Otsuka Foods is striving to educate consumers and expand its markets through its Better Health through Foods Project, which aims to help people establish new healthy eating habits.

#### Transportation and Warehousing

Otsuka Warehouse carries out the Otsuka Group's logistics operations. The company designs logistics matched to customers' needs, and builds and operates logistics systems to reduce distribution costs and improve distribution quality. In addition to business-to-business (B-to-B) logistics, services to support direct sales were launched in 2006, and the volume of orders is showing steady growth.

As a member of the global community, Otsuka Warehouse uses modal shift and collaborative distribution to promote environment-friendly logistics that reduce  $CO_2$  emissions.



## **Electronic Equipment**

Otsuka Electronics develops, manufactures, and markets optical evaluation/inspection equipment for LED light-source luminance and liquid crystal display (LCD) panel materials and finished products, as well as medical equipment and clinical diagnostic equipment. With the recent expansion in the application of electronic and lighting equipment fitted with LEDs, the company's LED evaluation/inspection equipment is widely used.



## Americas

The pharmaceutical segment in the Americas made smooth progress with strong sales of the antipsychotic *ABILIFY*, which is co-promoted with BMS. Prescriptions for the new aquaretic *SAMSCA*, which triggers the excretion of water only, are also increasing, with steady growth in the number of medical institutes using the drug since it was launched in 2009.

In the nutraceutical segment, the top U.S. vitamin brand, *Nature Made*, manufactured and marketed by Pharmavite LLC., a subsidiary company, is driving the nutraceutical business in the U.S.

#### **Main Operating Companies**





## Otsuka America Pharmaceutical, Inc. (OAPI) (Rockville, Maryland)

Established in 1989, OAPI today carries out marketing and sales of pharmaceuticals and medical devices in the U.S. OAPI currently handles the antipsychotic *ABILIFY*, the aquaretic *SAMSCA*, IV *BUSULFEX*, a drug administered prior to bone marrow transplant to treat chronic myelogenous leukemia, *BreathTek*, a kit for diagnosing *Helicobacter pylori* infection, and the antiplatelet agent *Pletal*.



## Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) (Princeton, New Jersey)

OPDC conducts clinical development covering a range of disorders in areas including the central nervous system, cardiovascular, oncology, ophthalmology and infectious diseases as a global development center for the pharmaceutical products of Otsuka Pharmaceutical.

## Otsuka Maryland Medicinal Laboratories, Inc. (OMML) (Rockville, Maryland)

A basic research facility established in 1985 as the Otsuka Group's first research facility in the U.S., OMML conducts basic research to support clinical trials and drug discovery research in conjunction with Otsuka Pharmaceutical.



## Pharmavite LLC (Northridge, California)

Manufactures and sells *Nature Made* supplements and the *SOYJOY* fruit soy bar. *Nature Made* is recognized as the No. 1\*
supplement in the U.S. in terms of retail sales.



\*2010 Nielsen data: Share of sales in the distribution market in supermarkets, drug stores, mass retailers, and membership stores.

## CG Roxane, LLC (Olancha, California)

Sources, bottles, sells, and exports to Japan CRYSTAL GEYSER ALPINE SPRING WATER.



(Affiliated company)

## Europe

The antipsychotic *ABILIFY*, antiplatelet agent *PletaI*, bronchodilator *Meptin*, and aquaretic *SAMSCA*, which was launched in Europe in 2009, all posted strong growth for the pharmaceutical segment in Europe.

Nutrition & Santé SAS, a Group company and the European leader in the functional and dietetic foods market, contributed to the expansion of the nutraceutical business in Europe.

#### **Main Operating Companies**







## Otsuka Pharmaceutical Europe Ltd. (Middlesex, United Kingdom)

Central office for European marketing and sales of medicinal products and medical devices, with offices in the U.K., France, Germany, Italy, Sweden and Spain. Otsuka Europe's products are: SAMSCA, ABILIFY, Pletal, Adacolumn, Mikelan, and Sprycel.

## Nutrition & Santé SAS (Revel, France)

Develops, manufactures, markets and sells health food, functional food, and sports nutrition food, primarily in Europe. Major brands include *Gerblé, Gerlinéa*, and *Isostar*.



#### ALMA S.A. (Orne, France)

(Affiliated company)

With bottling plants at natural springs across Europe, handles many brands including *CRISTALINE* and *COURMAYEUR* mineral water.







### Hebron S.A. (Barcelona, Spain)

Manufactures and sells foaming agents, plastic additives, and pharmaceutical intermediates within Europe, and exports to the Middle East and Africa.



## Asia and Middle East

The pharmaceutical segment in Asia and the Middle East was built upon a foundation in the intravenous solution business that the Group began cultivating in the 1970s. The segment has expanded mainly around local subsidiaries in South Korea, China, and Indonesia. Otsuka Medical Devices Co., Ltd., which was established in 2011 as a holding company to oversee the Group's medical devices business, is leading the expansion of this business segment in Asia, especially China.

In the nutraceutical segment, sales of Pocari Sweat significantly increased, especially in Indonesia and China due to efforts to meet local needs. This contributed to the growth of the business.

#### **Main Operating Companies**

## **China Otsuka** Pharmaceutical Co., Ltd. (Tianjin, China)

The Otsuka Group has a long history in China, beginning with the establishment of China Otsuka in 1981 as China's first pharmaceutical joint venture with a foreign company. China Otsuka currently has more than 1,000 employees, and handles basic intravenous solutions, preparations in ampoule, and ophthalmic solutions.



(Shanghai, China) (Non-consolidated subsidiary)

A basic research institution and one of three centers of the basic research network (Japan, the

U.S., and China) working to create innovative

drugs, with research focusing on infectious diseases and the central nervous system.

**Otsuka Shanghai** 

**Research Institute** 

## Otsuka Chemical India Ltd. (Delhi, India)

Manufactures and sells the pharmaceutical intermediate GCLE as a raw material for cephalosporin antibiotics, which are gaining



## Shanghai Otsuka Foods Co., Ltd. (Shanghai, China)

The company strives from day to day to produce high-quality products to provide Chinese consumers with "delicious, safe, reassuring, and healthy" foods. In an effort to open up the Chinese market, the company has sold Otsuka Set Cooked Rice since 2005. Later it introduced Chinese consumers to new choices such as Morning Rice Porridge, Japanese Style Curry Rice, Fish Eggs Curry Noodles, and Dream Curry Jiang.



a growing share of the Indian market.



## Thai Otsuka Pharmaceutical Co., Ltd. (Bangkok, Thailand) (Affiliated company)

Established in 1973, Thai Otsuka was the first overseas member of the Otsuka Group and is headquartered in Bangkok, Thailand. Today the company manufactures and sells basic intravenous solutions, amino acid intravenous solutions, and medical foods as part of its clinical nutrition business. As a trusted manufacturer of high-quality products, the company began exporting its basic intravenous solution products to Japan this year. Thai Otsuka also has the largest share of the hospital market for medical foods in Thailand.



## P.T. Amerta Indah Otsuka (Jakarta, Indonesia)

Manufactures and sells Pocari Sweat and sells SOYJOY in Indonesia. Sales of Pocari Sweat continue to grow in the ASEAN market and the second Pocari Sweat factory in Indonesia was completed in 2010.



# **Basic Approach**

The Otsuka Group engages in the challenge of conducting research and development into innovative, creative pharmaceutical and nutritional products with the objective of contributing to medical care and the health of people worldwide. The Group strives to live together harmoniously with local communities and the natural environment while aiming to live up to the trust of stakeholders.

# **Corporate Governance Framework**

Below is a diagram of Otsuka Holdings' corporate governance framework.

## Corporate organization

As a company with a board of corporate auditors, Otsuka Holdings has established a Board of Directors and a Board of Statutory Auditors, and engages an audit firm. The Company pursues sound business management by filling more than half the seats on its Board of Statutory Auditors with external auditors and by increasing the Board of Statutory Auditors' monitoring capabilities.

The articles of incorporation specify that the number of directors shall not exceed 18 in order to enable substantive discussion during Board meetings. The articles of incorporation also specify that the number of members of the Board of Statutory Auditors shall not exceed five.

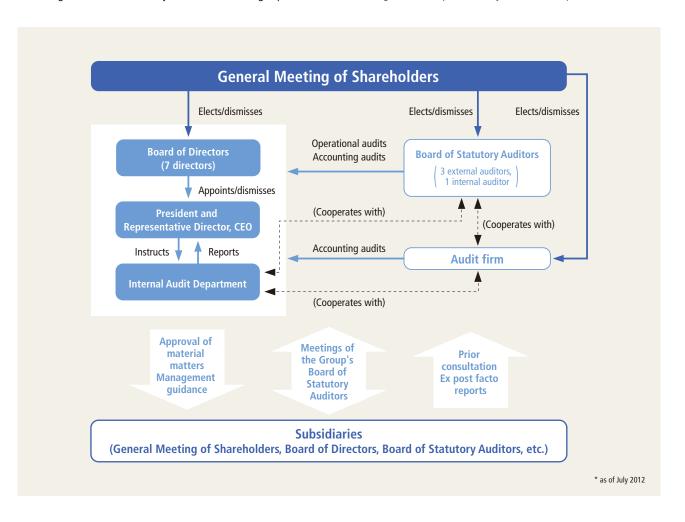
## Directors & the Board of Directors

In accordance with the Board regulations, the Board of Directors convenes once a month and holds extraordinary meetings as necessary to make important business decisions and supervise the execution of operations. As of the date of submission of this report, there are seven directors.

Information related to directors' performance of duties is stored and managed appropriately and reliably and maintained in an accessible format where needed, in accordance with the Company Documents Management Rules.

# Statutory Auditors and the Board of Statutory Auditors

Otsuka Holdings has adopted a statutory auditor system. Each statutory auditor attends and expresses opinions in meetings of the Board of Directors and monitors the legality and soundness of management as represented by the directors' performance of their



duties, with audits by the Board of Statutory Auditors at the core of this process.

Systems have been put in place for statutory auditors to interview directors and employees about the status of business execution, to review internal consultation documents and other important documents pertaining to business execution, and to promptly make reports on the execution of operations when asked to do so in order to ensure that audits by statutory auditors are conducted effectively. A Statutory Auditor's Office has been established to assist the duties of statutory auditors. It conducts the work of convening meetings of the Board of Statutory Auditors and assisting in the duties of statutory auditors independent of the chain of command of Board directors.

Furthermore, statutory auditors share information and exchange opinions as appropriate with relevant departments such as the Internal Audit Department, Internal Control Department, Administration Department, and Corporate Finance and Accounting Department, as well as the audit firm, in an effort to improve the effectiveness of their audits.

Otsuka Holdings does not establish committees. Statutory Auditor Hiroshi Sugawara holds qualifications as a certified public accountant and has considerable expertise in financial affairs and accounting.

## External Statutory Auditors

The statutory auditors monitor the Board of Directors, which makes business decisions and manages and supervises the execution of operations. Otsuka Holdings has strengthened this monitoring of management by appointing external auditors to three of the four statutory auditor positions.

Objective, neutral monitoring of management from the outside is regarded as an important aspect of corporate governance. Otsuka Holdings believes that the monitoring of its management from the outside is sufficiently carried out through auditing by a Board of Statutory Auditors that includes three external auditors. This is why the Company has not appointed external directors.

As statutory auditors, external auditors share information and exchange opinions as appropriate with relevant departments such as the Internal Audit Department, Internal Control Department, Administration Department, and Corporate Finance and Accounting Department, as well as the audit firm, in an effort to improve the effectiveness of their audits.

As of the date of submission of this report, external statutory auditors Yasuhisa Katsuta and Norikazu Yahagi each held 100,000 shares of common stock in Otsuka Holdings. Katsuta is also an external statutory auditor for Otsuka Pharmaceutical Co., Ltd. Otsuka Pharmaceutical is a wholly owned subsidiary of Otsuka Holdings. External statutory auditor Yahagi is also an

external auditor for Nippon Office Systems Ltd., Square Enix Holdings Co., Ltd., and T.D.I Co., Ltd. Otsuka Holdings has no business relationships with these companies. External statutory auditor Hiroshi Sugawara is also an external statutory auditor for Otsuka Pharmaceutical and a vice president at Will Capital Management Co., Ltd. Otsuka Holdings has no business relationship with Will Capital Management.

Otsuka Holdings has designated external statutory auditors Sugawara and Yahagi as independent officers, as regulated by the Tokyo Stock Exchange, and notified the Tokyo Stock Exchange thereof.

The criteria for appointment of external statutory auditors is as follows:

External statutory auditors must be capable persons with abundant knowledge and experience in various fields. They must be able to sufficiently demonstrate management oversight of the directors by performing audits of management from a neutral and objective viewpoint. One criterion for ensuring neutrality and objectivity is independence from the management team, and the Company demands that there be no risk of a conflict of interest with general shareholders developing between the Company and a candidate. The Company has not established formal criteria pertaining to past duties and career history, other than having not engaged in the administration of business matters in a Group company, as criteria for independence. However, bearing in mind the Criteria for Judgment of Independence specified by the Tokyo Stock Exchange,\* the Company does stress that candidates must be able to make judgments substantially independent from managers, which it uses as an appointment criterion for external statutory auditors.

- \* If a person designated as an independent officer falls under any of the following items "a." to "e.," the Company must disclose the reason the person is designated as an independent officer and deemed as having no risk of a conflict of interest with general shareholders even given this fact.
  - a. An operating officer, etc. (referring to a person who is or was an operating officer; the same hereinafter) of the parent company or fellow subsidiaries of the company concerned
  - A person who has the company concerned as his/her main business partner or an operating officer, etc. or is a main business partner of the company concerned or an operating officer, etc. of that business partner
  - c. A consultant, accounting professional, or legal professional who has gained a substantial amount of money or other assets besides officer's compensation or remuneration from the company concerned; or a person who belongs or used to belong to an entity, such as a corporation or association, that has gained said assets
  - d. A principal shareholder in the company concerned
  - e. A close relative of a person indicated in either (a) or (b) below (excluding persons who are not principal figures):
    - (a) A person indicated in "a." to "d." above
    - (b) An operating officer, etc. of the company concerned or its subsidiary (including, if an external statutory auditor is to be designated an independent officer: a director who is not an operating officer; or a person who was a director who was not an operating officer, an accounting advisor, or a person who was an accounting advisor)

# Internal Audit Department

The Company operates an Internal Audit Department under the direct control of the president. The department regularly conducts audits based on the Internal Audit Rules to verify that operations are being executed appropriately and efficiently regarding the assets and overall affairs of the Company and its affiliated companies, and it submits audit reports to the president, directors, and statutory auditors. When the need for improvements is indicated, the department issues recommendations for improvement and afterward confirms the status of implementation in an effort to optimize the performance of duties. The department also shares information with statutory auditors and the audit firm and in other ways cooperates with them.

# •Internal Control Department

The Company operates an Internal Control Department to handle internal controls relating to financial reporting by the Company and its affiliated companies. The department formulates rules and manuals pertaining to internal controls, provides training and ensures thorough familiarity with operational rules, continuously monitors the status of operation in cooperation with the Internal Audit Department, and has established a system in which the assessment of internal controls covering executives is conducted reliably.

## Corporate Officer System

Otsuka Holdings has adopted a corporate officer system that clearly divides the role of corporate officer, which is to execute business operations, from that of the Board of Directors, which is to make business decisions and exercise a supervisory function. This system ensures management transparency and the efficiency of business operations.

## Status of Account Auditing

Otsuka Holdings has signed an auditing agreement with Deloitte Touche Tohmatsu Limited as its auditing firm, which audits the Company's accounts from a fair and impartial stance. The certified public accountants who audited the Company's accounts were Tatsuaki Kitachi, Yukitaka Maruchi, and Kenichi Kimura. They were assisted by ten certified public accountants and five other people. All of the certified public accountants who audited the Company's accounts have done so continuously for less than seven years.

# System for Ensuring Appropriateness of Operations in Otsuka Holdings and the Corporate Group Consisting of Its Subsidiaries

As a holding company responsible for maximizing the corporate value of the Otsuka Group, Otsuka Holdings has established a system to ensure the appropriateness of operations from a Group-wide perspective.

Affiliated companies report matters prescribed in the Affiliated Companies Management Rules to Otsuka Holdings as needed, and the approval of Otsuka Holdings is needed for important matters in these reports. In this way, we have established a system for coordination within the Otsuka Group.

Otsuka Holdings and its main subsidiaries have adopted a statutory auditor system. A Board of Statutory Auditors has been established so that several statutory auditors can audit the directors' performance of duties and thereby increase their effectiveness. Statutory auditors attend meetings of the Board of Directors as well as other important meetings. In accordance with the auditing guidelines and auditing plan established at the meetings of the Board of Statutory Auditors, the auditors audit the execution of operations by the directors. Also, as a general rule, a meeting of the Group's statutory auditors is convened twice a year.

Auditors from each company share information and strengthen links and are requested to report on each company's business conditions.

Additionally, Otsuka Holdings' Internal Audit Department, pursuant to the Internal Audit Rules, supervises or conducts audits that also include affiliated companies. In this way, the Company has established a cross-divisional risk management system and compliance system that ensure the appropriateness of operations throughout the Group.

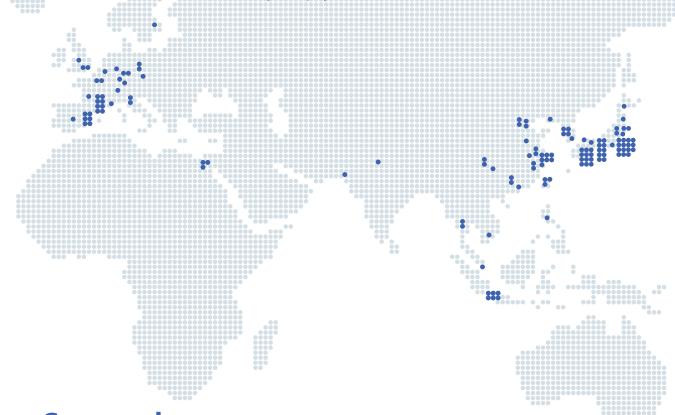
# **Risk Management System**

To defend against latent risks relating to the performance of duties, Otsuka Holdings has established rules regarding risk management, provides thorough risk management training to all employees, and has established a risk management system. In the event of an unforeseen incident, the Company will respond promptly, set up risk management committees as needed, and establish a system to minimize the spread of damage.

# Worldwide Network

as of March 31, 2012

The Otsuka Group consists of 156 companies worldwide operating with the common theme of 'health.' The Group comprises 67 consolidated subsidiaries and 13 affiliates accounted for by the equity method.



# Group Companies (•: consolidated subsidiaries and affiliates accounted for by the equity method)

## [ Japan ]

- Otsuka Holdings Co., Ltd.
- Otsuka Pharmaceutical, Co., Ltd.
- Taiho Pharmaceutical, Co., Ltd.
- Otsuka Pharmaceutical Factory, Inc.
- Otsuka Chemical Co., Ltd.
- Otsuka Warehouse Co., Ltd.
- Otsuka Medical Devices Co., Ltd.
- EN Otsuka Pharmaceutical Co., Ltd.
- J.O.Pharma Co., Ltd.
- JIMRO Co., Ltd.
- Okayama Taiho Pharmaceutical Co., Ltd.
- Otsuka Chilled Foods Co., Ltd.
- Otsuka Electronics Co., Ltd.
- Otsuka Foods Co., Ltd.
- Otsuka MGC Chemical Company, Inc.
- Otsuka Packaging Industries Co., Ltd.
- Otsuka Techno Corporation
- Earth Chemical Co., Ltd.
- Earth Environmental Service Co., Ltd.
- Agri Best Co., Ltd.
- Chuo Electronics Measurement Co., Ltd.
- Dairin Integrated Transportation Co., Ltd.
- GlycoGene, Inc.
- HAIESU Service Co., Ltd.
- Heartful Kawauchi Co., Ltd
- ILS Inc.
- KiSCO Co., Ltd.

- Naruto Cruise Service Co., Ltd.
- Nippon Pharmaceutical Chemicals Co., Ltd.
- Organ Technologies Inc.
- Otsuka Furniture Manufacturing and Sales Co., Ltd.
- Otsuka Naruto Development Co., Ltd.
- Otsuka Ohmi Ceramics Co., Ltd.
- Otsuka Ridge Co., Ltd.
- Otsuka Turftech Co., Ltd.
- Awa Union Transportation Co., Ltd.
- Bean Stalk Snow Co., Ltd.
- Big Bell Co., Ltd.
- Earth Biochemical Co., Ltd.
- Kitasato Otsuka Biomedical Assay Laboratories Co., Ltd.
- Marukita Furniture Center
- Naruto Salt Mfg. Co., Ltd.
- NEOS Corporation
- NICHIBAN Co., Ltd.
- RIBOMIC Inc.
- Tokushima Air Terminal Building Co., Ltd.
- Tokushima Vortis Co., Ltd.
- Yoshino Farm

## [ Americas ]

- Otsuka America, Inc.
- Cambridge Isotope Laboratories, Inc.

Membrane Receptor Technologies LLC

- CIL Isotope Separations, LLC
- Crystal Geyser Water Company

- Otsuka America Manufacturing, LLC
- Otsuka America Pharmaceutical, Inc.
- Otsuka Maryland Medicinal Laboratories, Inc.
- Otsuka Pharmaceutical Development & Commercialization Inc.
- Pharmavite LLC
- Ridge Vineyards, Inc.
- Soma Beverage Company, LLC
- Otsuka Canada Pharmaceutical Inc.
- •2768691 Canada, Inc.
- CG Roxane LLC
- American Peptide Company, Inc.
- Oncomembrane Inc.
- Otsuka America Foods Inc.
- Otsuka Chemical do Brasil Ltda.
- Otsuka Global Insurance, Inc.
- Taiho Pharma U.S.A., Inc.
- Crystal Geyser Brand Holdings, LLC
- Galenea Corp.
- Graceland Fruit, Inc.

### [ Asia, others ]

- Korea Otsuka Pharmaceutical Co., Ltd.
- Taiwan Otsuka Pharmaceutical Co., Ltd.
- Chongging Otsuka Huayi Chemical Co., Ltd.
- Otsuka (China) Investment Co., Ltd
- Shanghai Otsuka Foods Co., Ltd.
- Sichuan Otsuka Pharmaceutical Co., Ltd.
- Suzhou Otsuka Pharmaceutical Co., Ltd.

## Number of operations and employees of Otsuka Group

	Worldwide	Japan	Overseas
Companies	156	48	108
Factories	172	47	125
Research Institutes	44	30	14
Employees	Approx. 40,000	Approx. 18,000	Approx. 22,000



History of Otsuka's global business expansion

1973North America (United States), Asia (Thailand)	2006India
1977Africa (Egypt)	2007South America (Brazil)
1979Western Europe (Spain)	2008Eastern Europe (Czech Republic)
1981China	

- Tianjin Otsuka Beverage Co., Ltd.
- Zhejiang Otsuka Pharmaceutical Co., Ltd.
- Otsuka Chemical (India) Private Limited
- P.T. Amerta Indah Otsuka
- P.T. Merapi Utama Pharma
- P.T. Otsuka Indonesia
- P.T. Otsuka Jaya Indah
- P.T. Widatra Bhakti
- P.T. Lautan Otsuka Chemical
- Egypt Otsuka Pharmaceutical Co., S.A.E.
- Giant Harvest Limited
- Otsuka Pakistan Ltd.
- Dong-A Otsuka Co., Ltd.
- King Car Otsuka Co., Ltd.
- China Otsuka Pharmaceutical Co., Ltd.
- Guangdong Otsuka Pharmaceutical Co., Ltd.
- Micro Port Medical (Shanghai) Co., Ltd.
- VV Food & Beverage Co., Ltd.
- Thai Otsuka Pharmaceutical Co., Ltd.
- Microport Scientific Corporation
- KOC Co., Ltd.
- Norea OIAA Co., Ltd.
- Otsuka Electronics Korea Co., Ltd.
- Otsuka Tech Electronics Co., Ltd.
- Dalian Otsuka Furniture Co., Ltd.
- Hangzhou Linan Kangle Pharmaceutical Co., Ltd.
- ILS (Shanghai) Co., Ltd.
- Leshan Otsuka Techno Co., Ltd.

- MOC Chemicals Trading (Shanghai) CO., LTD.
- Nanjing Otsuka Techbond Techno Co., Ltd.
- Otsuka (Shanghai) Foods Safety Research & Development Co., Ltd.
- Otsuka Beijing Research Institute
- Otsuka Electronics (Suzhou) Co., Ltd.
- Otsuka Electronics Shanghai CO., Ltd.
- Otsuka Pharmaceutical (H.K.) Ltd.
- Otsuka Shanghai Research Institute
- Otsuka Sims (Guangdong) Beverage Co., Ltd.
- Taiho Pharmaceutical of Beijing Co., Ltd.
- Zhangjiagang Otsuka Chemical Co., Ltd.
- TAIHO PHARMA SINGAPORE PTE. LTD.
- Otsuka Saha Asia Research Co., Ltd.
- Otsuka (Philippines) Pharmaceutical, Inc.
- Otsuka Import Export LLC
- Otsuka Trading Africa Co. (SAE)
- Xiamen United Medical Instruments Co., Ltd.
- Otsuka OPV Co., Ltd.
- Diatranz Otsuka Limited
- Achieva Medical Limited

# [ Europe ]

- Otsuka Pharmaceutical Europe Ltd.
- Otsuka Pharmaceuticals (U.K.) Ltd.
- Euriso-Top S.A.S
- Laboratoires Dietetique et Sante SAS
- Nardobel SAS
- Nutrition & Nature SAS

- Nutrition & Sante SAS
- Otsuka Pharmaceutical France SAS
- Advanced Biochemical Compounds, GmbH
- Cambridge Isotope Laboratories (Europe), GmbH
- Euriso-Top GmbH
- Otsuka Pharma GmbH
- Nutrition & Sante Italia SpA
- Hebron S.A.
- Nutrition & Sante Iberia SL
- Otsuka Pharmaceutical, S.A.
- Nutrinat AG
- Otsuka Pharma Scandinavia AB
- Nutrition & Sante Benelux SA
- ALMA S.A.
- Taiho Pharma Europe, Limited
- KiSCO International SAS
- Otsuka Frankfurt Research Institute GmbH
- Otsuka Novel Products GmbH
- Otsuka Pharmaceutical Italy S.r.l.
- Trocellen Iberica S.A.
- Otsuka S.A.
- Interpharma Praha, a.s.
- Era Endoscopy S.r.l.

CSR

# Social Responsibility

Based on its corporate philosophy, "Otsuka-people creating new products for better health worldwide," the Otsuka Group is deeply committed to the natural environment and the local communities it operates in. Its social and cultural activities are part of its mission to contribute to the health and well-being of people worldwide.

# Relief after the Great East Japan Earthquake

Immediately after the Great East Japan Earthquake struck on March 11, 2011, the Otsuka Group set up a crisis management headquarters and oversaw close coordination within the Group. Otsuka's Sendai Branch, which is in the afflicted area, gathered its stocks of products on hand and delivered them the morning after the earthquake to emergency response hospitals and local government disaster response headquarters. The Tokyo head office coordinated with government ministries and agencies concerned and industrial organizations and arranged for the Group's pharmaceuticals, beverages, and food products to be used as relief goods.

In response to calls from Group companies around the world desiring to provide support, Otsuka donated the equivalent of ¥10,000 per employee (¥390 million) to the Japanese Red Cross Society based on the consensus of its 39,000 employees.\*

\* Including those at non-consolidated Group companies



# Letters of Appreciation Received from Miyagi Prefecture and the Tokyo Fire Department for Support Given after the Great East Japan Earthquake

In February 2012, Otsuka Pharmaceutical received a letter of appreciation from Miyagi Prefecture for the Otsuka Group's rapid response and later support.

Additionally, in 2010 Otsuka Pharmaceutical signed an agreement with the Tokyo Fire Department Supporters Foundation, which provides physical support to the Tokyo Fire Department, regarding the procurement of foodstuffs during disasters. The Company put in place a system to supply needed beverages and food to support the Tokyo Fire Department's operations in the event of an earthquake rated 5 or greater on the Japanese seismic scale hitting Tokyo.

After the Great East Japan Earthquake, the Company provided Group products for free to teams being dispatched to the afflicted areas, in addition to supplying the beverages and food promised in the agreement. In response, a letter of appreciation was received from the fire chief of the Tokyo Fire Department.



# Certificate of Commendation Received from the Ambassador of Japan to Pakistan for the Otsuka Welfare Clinic's Eight Years of Medical Relief for Afghan Refugees in Pakistan

Otsuka Pharmaceutical, Otsuka Pakistan, and 25 Group companies across the Asian and Arab regions established the Otsuka Welfare Clinic in 2003 to provide relief to Afghan refugees in Peshawar, the capital of Pakistan's former North-West Frontier Province. Otsuka received a certificate of commendation from the ambassador of Japan to Pakistan in recognition of the free



medical relief provided over the eight years since the clinic's establishment. Otsuka was commended for its noteworthy contribution to welfare in the region and how it has greatly helped to deepen the friendship between the two nations.

After the 9/11 terrorist attacks in the U.S. in 2001, refugees who had fled Afghanistan were placed in an environment with inadequate clothing, food, and shelter in refugee camps in Peshawar, a town close to the border. As a life-related company developing its business across Asia, the Otsuka Group wanted to directly support refugees on the ground. After repeated consideration, it was decided that it would establish a free medical clinic for the people in the refugee camps, who were without access to satisfactory healthcare.

About 260 people per day visit the clinic, which has seen more than 650,000 people thus far. Today the clinic, which has a full-time staff of eight, including midwives, pharmacists and three doctors, sees neighborhood residents in addition to refugees and has become a medical institution rooted in the community.

Going forward, the Otsuka Group will continue carrying out community-based projects that contribute to people's health.

# Otsuka Opens On-site Daycare Facility, "BeanStalk Kids Center Tokushima"



The Otsuka Group opened its first on-site daycare facility, called the BeanStalk Kids Center Tokushima, in April 2011. The facility is located in Tokushima Prefecture, where the Group has its origins. BeanStalk Kids Center Tokushima was named after the English folktale Jack and the Beanstalk, in which a bean is planted and then turns overnight into a giant beanstalk reaching up to

The spacious one-story building employs an architectural design that takes advantage of solar heat and light, while using wind and vegetation to create a comfortable space that remains cool without the use of air-conditioning on all but the hottest days. The facility offers a diverse program that is designed to foster active minds and spark children's interest in all kinds of things. The building, which makes ample use of cedar from Tokushima Prefecture, provides a safe and clean daycare environment in which to nurture the talents, creativity, and individuality of children, in cooperation with their families.

With the recent emphasis on work-life balance, the Group is considering the establishment of other daycare facilities both in and outside of Japan, as part of its efforts to provide conditions that enable employees to feel reassured about working while fulfilling their parenting duties.

# **New Kabuki Production** Third Season of Sistine Kabuki— A Japanese and Western Collaboration Goemon

On November 12 and 14, 2011, the new kabuki play, Goemon, by Shochiku Co., Ltd., was staged in the Otsuka Museum of Art's Sistine Hall, a three-dimensional, full-size recreation of the Sistine Chapel in the Vatican. The so-called Sistine Kabuki presented in the hall are all original, new Kabuki plays featuring Japanese and Western collaboration and contributions by local performers.

The production of *Goemon* combined Spanish flamenco and Japanese kabuki, with a special appearance by Shoji Kojima, a world-renowned flamenco dancer from Tokushima Prefecture, who was recognized in Japan as a Person of Cultural Merit in 2009. The spirited music of the flamenco guitar blended beautifully with traditional gidayu-style ballad narrative. Dynamic performances in the kabuki style of playing to the gallery included the titular character Goemon's midair stunts against the backdrop of brilliant ceiling paintings of the Book of Genesis by master artist Michelangelo. All this contributed to the appeal of the production.

The Otsuka Museum of Art was established in Naruto, Tokushima, in 1998 to commemorate the Otsuka Group's 75th anniversary. It is the world's only art museum to feature famous masterpieces reproduced on ceramic panels. From ancient to contemporary works, including ancient relics and church frescoes, over 1,000 pieces found in more than 190 galleries in 25 countries around the world are reproduced in their original size using Otsuka Ohmi Ceramics' special manufacturing technique. With the original colors preserved from fading, the esthetic value of the original works is well-

Going forward, the Otsuka Museum of Art will continue to propose various events and programs in an effort to unite with Tokushima's vision of the prefecture as a creator of culture.



Photo: SHOCHIKU Co., Ltd

Otsuka Museum of Art website

www.o-museum.or.jp/english

# Financial Highlights (Graphs 1, 3 and 4)

During the fiscal year ended March 31, 2012, the Japanese economy started to recover more strongly from the Great East Japan Earthquake and the operating environment for companies gradually improved.

Overseas, the economic outlook remained uncertain amid the sovereign debt crisis in Europe and high crude oil prices.

Against this backdrop, the Otsuka Group reported consolidated net sales of ¥1,154,574 million (2.4% increase from the previous year) for the fiscal year ended March 31, 2012, with operating income of ¥148,662 million (17.7% increase) and net income of ¥92,174 million (11.9% increase).

From the fiscal year, the Company changed its method of translating revenue and expense accounts of foreign subsidiaries and affiliated companies and its method of presentation for up-front licensing payments received. For comparative purposes, the figures for the previous fiscal year have been adjusted retrospectively.

# Operating Results by Business Segment (Graphs 2, 3, 4 and 5)

Net sales of the pharmaceutical segment were ¥782,248 million (4.1% increase from the previous year), consisting mainly of domestic sales of *ABILIFY*, *Mucosta*, *Pletaal*, *TS-1* and *ABILIFY* sales in the U.S. and Europe.

Net sales of the nutraceutical segment were ¥254,825 million (1.5% decrease from the previous year), consisting mainly of domestic sales of *Pocari Sweat*, *Oronamin C*, *SOYJOY* and *Nature Made* brand supplements as well as functional foods in the European market.

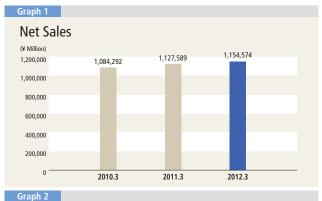
Net sales of the consumer products segment were ¥49,207 million (2.7% increase from the previous year), consisting mainly of sales of *CRYSTAL GEYSER*, *Java Tea* and *MATCH*.

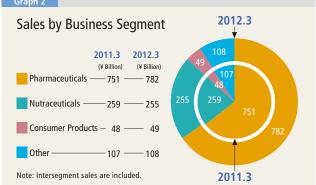
Net sales of the other segment were ¥108,603 million (1.6% increase from the previous year), consisting of sales of fine chemical and specialty chemical products, as well as revenues from the logistics business.

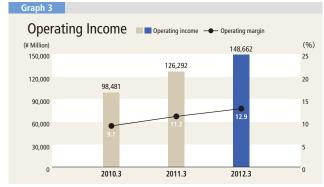
Selling, general and administrative expenses were ¥616,649 million (0.9% decrease from the previous year), resulting in an operating income of ¥148,662 million (17.7% increase from the previous year). Major components of selling, general and administrative expenses included salaries and bonuses (¥81,278 million), sales promotion expenses (¥174,380 million) and research and development expenses (¥159,230 million).

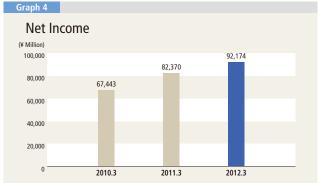
Other income (expense) was ¥6,257 million. Other income (expenses) included equity in earnings of unconsolidated subsidiaries and affiliated companies (¥1,216 million), foreign exchange loss (¥2,712 million), gain on change in equity interest (¥322 million), and loss on impairment of long-lived assets (¥2,685 million).

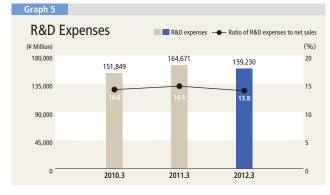
As a result, net income was ¥92,174 million (11.9% increase from the previous year).











# Financial Position (Graph 6)

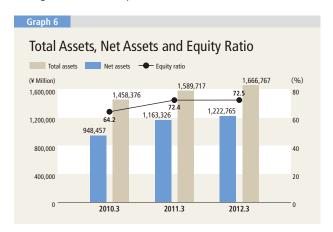
Total assets as of March 31, 2012 were ¥1,666,767 million, an increase of ¥77,050 million from the end of the previous fiscal year. The increase was due mainly to a ¥91,068 million increase in current assets resulting from a solid twelve-month performance and from part of a US\$ 200 million up-front licensing payment from Lundbeck under the global alliance agreement in central nervous system treatments combined with a ¥12,701 million decrease in investments and other assets.

Total current liabilities as of March 31, 2012 were ¥311,359 million, an increase of ¥35,801 million from the end of the previous fiscal year. The increase was due mainly to the increase in corporate taxes payable as a result of the solid twelve-month performance and the receipt of a US\$ 200 million up-front licensing payment from Lundbeck under the global alliance agreement in central nervous system.

Total long-term liabilities as of March 31, 2012 were \$132,643 million, a decrease of \$18,190 million from the end of the previous fiscal year. The decrease was due mainly to reclassification of the current

portion of unearned revenues (revenues to be recognized within a year), from long-term liabilities to current liabilities. The unearned revenues consisted of US\$ 400 million received from Bristol-Meyers Squibb in April 2009.

Total net assets as of March 31, 2012 stood at ¥1,222,765 million, an increase of ¥59,439 million from the end of the previous fiscal year. The increase was due mainly to the ¥65,443 million increase in retained earnings as a result of the positive net income.



# Cash Flows (Graph 7)

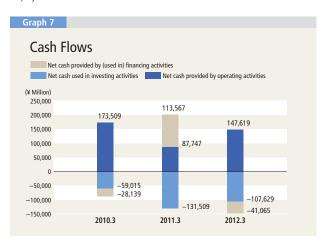
Cash and cash equivalents decreased by ¥3,132 million during the fiscal year ended March 31, 2012 to ¥384,194 million. Net cash provided by operating activities was ¥147,619 million, while net cash used in investing activities and financing activities were ¥107,629 million and ¥41,065 million, respectively.

Net cash provided by operating activities was ¥147,619 million in the fiscal year ended March 31, 2012, an increase of ¥59,872 million, compared to ¥87,747 million in the previous fiscal year. In addition to ¥142,405 million in income before income taxes and minority interests from the solid twelve-month performance (an increase of ¥19,375 million compared to ¥123,030 million at the end of the previous fiscal year), an increase in unearned revenue due to receipt of a US\$ 200 million up-front licensing payment from Lundbeck under the global alliance agreement in central nervous system treatments, an increase of ¥8,473 million (¥2,095 million in the previous fiscal year) in trade payables, and a payment of ¥34,422 million (¥59,942 million in the previous fiscal year) in income taxes are factors of this increase.

Net cash used in investing activities was ¥107,629 million in the fiscal year ended March 31, 2012, an increase of ¥23,880 million compared to ¥131,509 million in the previous fiscal year. Investing activities during the fiscal year ended March 31, 2012 included ¥36,034 million in purchases of property, plant and equipment, ¥21,060 million in purchases of investment securities, ¥17,435 million in proceeds from

sales and redemption of investment securities, and ¥47,504 million in payments into time deposits. Purchases of property, plant and equipment included acquisition of tangible fixed assets for pharmaceutical production facilities at the Tokushima Wajiki Factory and *Pocari Sweat* production facilities at the Saga Factory and updates of other existing facilities.

Net cash used in financing activities was ¥41,065 million in the fiscal year ended March 31, 2012 (net cash provided by financing activities for the previous fiscal year was ¥113,567 million). Financing activities during the fiscal year ended March 31, 2012 included ¥23,834 million in repayments of long-term debt and ¥26,776 million in payment of dividends.



# **Operational Risks**

The scope of the Group's operations and the number of industries in which the Group operates means that the Group's business performance is exposed to various risks.

Below are the major risk factors that could have a major impact on the Group's financial position and results of operations.

This explanation is not intended to be complete and there may be other risks affecting the Group's performance not listed below. Forward-looking information reflects our judgment on the basis of information available as of March 31, 2012.

# (1) Our ability to pay dividends is substantially dependent on our subsidiaries and affiliated companies.

As a holding company, dividends and management fees from our subsidiaries and affiliated companies represent a substantial portion of our cash flow. Under some circumstances, various statutory or contractual provisions may restrict the amount of dividends that our subsidiaries and affiliated companies are able to pay us. Also, if our subsidiaries and affiliated companies do not have sufficient earnings, they will be unable to pay dividends and management fees, and we may in turn be unable to pay dividends on our common stocks.

# (2) Our pharmaceutical products could have previously unknown side effects

While our pharmaceutical products are subjected to clinical testing during the approval process, there are inherent restrictions on the adequacy of such tests, including the limited number of patients on which such tests are conducted and limited ability to perform long-term monitoring. There can therefore be no assurance that our pharmaceutical products will not exhibit previously unknown side effects. In the event that such unknown side effects are discovered, we may be required to recall and terminate sales of such products. We could also be subject to liability to users of such products. Although we take out product liability insurance, such insurance coverage is expensive and may be difficult to maintain on acceptable terms or at all. In addition, our insurance coverage is subject to limits, and claims brought against us could significantly exceed such limits. Damage to our reputation and brand value could also arise. As a result, our business, financial condition and results of operations could be materially and adversely affected.

# (3) Research and development for pharmaceutical products is subject to uncertainties

Researching and developing a new product requires significant time. It is costly and subject to numerous factors that may delay or prevent the development of new pharmaceutical products. We are also subject to applicable laws and regulations in Japan and other jurisdictions that regulate pharmaceutical products, including approval processes that involve significant uncertainties in terms of the length of time required for approval and whether the products meet the criteria of regulatory authorities with respect to efficacy and safety requirements. These could lead to unexpected delays in, or the termination of, our plans to introduce new products after significant investments of financial and human resources. In addition, there can be no assurance that any investment in research and development will be recouped, even if we are successful in acquiring regulatory approval or commercializing the relevant products. As a result, we may not be able to earn the return on investment that we originally anticipated or any return, and our financial condition and results of operations could be materially and adversely affected.

# (4) We are subject to risks related to our reliance on a specific product for a significant portion of our total net sales

Sales of our top-selling pharmaceutical product *ABILIFY* constitute more than 30% of our total consolidated net sales.

If the sales of this product decrease due to competition from other products, including generic versions of the product becoming available upon the expiration of related patents, or otherwise, our financial condition and results of operations will be materially and adversely affected.

We maintain a commercialization agreement with Bristol-Myers Squibb Company ("BMS"), to co-develop and co-promote *ABILIFY* in the U.S. Under the terms of the agreement, BMS retains the right to terminate the contract before the expiration date upon the advent of a generic competitor to *ABILIFY*. We will be required to make a payment to BMS based on a pre-determined schedule upon such termination, and this would have an adverse effect on our financial position and results of operations.

Note: The protection period for the substance patent of *ABILIFY* will expire in January 2016 in Japan (including the two-year pediatric exclusivity), in April 2015 in the U.S. (including the six-month pediatric exclusivity) and in October 2014 in Europe.



# (5) We are subject to risks related to government policies to reduce medical costs

A manufacturer of pharmaceutical products in Japan must have new products listed on a National Health Insurance ("NHI") price list published by the Ministry of Health, Labor and Welfare ("MHLW"). The NHI price list provides rates for calculating the price of pharmaceutical products used in medical services provided under various public medical care insurance systems. Prices on the NHI price list are subject to revision, generally once every two years, on the basis of the actual prices at which the pharmaceutical products are purchased by medical institutions after discounts and rebates. The MHLW, concerned by the prospect of spiraling healthcare costs, has been exerting pressure to restrain drug costs.

Similarly, in the U.S., the second largest market for our pharmaceutical products, managed care organization, insurance companies and the government have been promoting the use of generic drugs and there have been increasing pressure to lower prescription drug prices. Further implementation of such policies could have a material and adverse effect on our financial condition and results of operations.

# (6) Some of our products are subject to risks related to consumer sentiment

We sell products in our Nutraceuticals business and Consumer Products business that are subject to fluctuations in demand based on consumer sentiment which in turn is subject to seasonal changes and the general economic environment. A worsening of consumer sentiment could have a material adverse effect on such businesses.

### (7) We are subject to risks related to food safety

In recent years, there have been incidents in Japan where concerns over tainted foods, including foods containing highly toxic materials, have led to widespread criticism of food companies, and the sensitivity to food safety in Japan remains high. If our products are found or suspected to have safety problems, sales of our products and our reputation could be materially and adversely affected.

# (8) We depend on outside sources for the materials for our products

We are generally dependent on third-party sources for the raw materials used in our products. The price and availability of the raw materials for our products, including chemical compounds, agricultural products, minerals and other commodities, are subject to the effects of weather,

natural disasters, market forces, economic environment, fuel costs and foreign exchange rates. If our cost for such materials increases, we may not be able to make corresponding increases in the prices of our products due to market conditions or our relationships with customers, and as a result, our profitability could be materially and adversely affected.

# (9) We are subject to risks related to laws and regulations

Our Pharmaceutical business is subject to extensive regulation under the Pharmaceutical Affairs Law in Japan and relevant laws in other jurisdictions in which we operate. Our Other businesses are also subject to regulation in Japan under the Food and Sanitation Law, recycling-related laws, and other regulations, as well as similar laws in other jurisdictions. In the event that we are found to have violated any such laws and regulations, we may be required to recall the relevant product, terminate sales of such product or suspend operations of the relevant business. In some cases where we believe there is a risk of violation, we may decide to take such actions voluntarily. Furthermore, we may become subject to increased compliance costs or restrictions on our business operations as a result of future changes in applicable laws and regulations.

# (10) Our pharmaceutical products are subject to significant competition

The pharmaceutical industry is highly competitive, requiring us to maintain ongoing, extensive research for technological innovations. In addition, new products of competitors or the development of new medical technologies and treatments could make our products or technologies lose their competitiveness or become obsolete. Our proprietary rights to our pharmaceutical products are generally based on related patents. Upon the expiration of such patents, our products will become open to competition from generic drugs, which are bioequivalent but lower in price, and could lead to a decline in demand for our products. An increase in competition due to any of the foregoing factors could have a material adverse effect on our financial condition and results of operations.

# (11) We are subject to risks related to the infringement of intellectual property rights

If our patent and other intellectual property rights are infringed by third parties, we may not be able to take full advantage of existing demand for

our products. We are also subject to the risk of infringement claims directed at us by third parties. If we are found to have infringed the intellectual property rights of others, or if we agree to settle under such terms, we may be required to recall the relevant products, terminate manufacturing and sales of such products, or pay significant damages or royalties.

Currently, we have filed patent infringement actions against a number of generic drug companies for the product *ABILIFY*. The U.S. District Court issued the judgment of first instance dated November 15, 2010 and the judgment of second instance dated May 7, 2012 in favor of Otsuka Pharmaceutical Co., Ltd. However, one of these generic drug companies has filed notices of appeal to the U.S. Court of Appeals for the Federal Circuit challenging the May 7, 2012 judgment.

Any unfavorable ruling, decision or settlement resulting in the launch of generic versions of *ABILIFY* in the U.S. would likely result in substantial decrease in the sales of *ABILIFY* in the U.S., which would have a material adverse effect on our financial condition and results of operations.

# (12) We are subject to litigation risk

We are subject to the risk of litigation from third parties with respect to the operation of our business, including claims related to product liability, labor issues, infringement of intellectual property rights, contract disputes and environment issues. In the event of an adverse decision or settlement, our business, financial condition and results of operations could be materially and adversely affected.

# (13) We are subject to the risk of natural disasters and accidents

While our facilities, including our manufacturing facilities, are broadly dispersed geographically, a significant number of such facilities are concentrated in Japan. We thus continue to be subject to stoppage, damage, and other risks related to natural disasters such as earthquakes and typhoons as well as accidents. If our facilities are damaged or destroyed due to such incidents, the manufacture or distribution of materials and products could be significantly disrupted, consumer confidence in us could decrease, and we may incur significant expenses to repair, reconstruct or replace such facilities.

# (14) Our results of operations and reputation could be harmed if we are found or perceived to have violated environmental regulations

We are subject to various environmental laws and regulations in the various regions in which we operate. In the event that we are found to have violated such laws and regulations, including those relating to wastewater discharge, air emissions, handling of hazardous materials, disposal of solid and hazardous wastes, and remediation of soil and groundwater contamination, we could be subject to significant fines, imposition of damages, clean-up costs, suspension of production, cessation of operations or a delay in disposition of unused property. There can be no assurance that there will not be any environmental violation in the future that results in a material adverse effect on our financial condition and results of operations. In addition, even the perception of such violations could have an adverse affect on our reputation and thus negatively affect our operational results.

## (15) We are subject to market risk

In the fiscal year ended March 31, 2012, 50.2% of our net sales were from customers outside of Japan, and we believe that a significant portion of our net sales will continue to be based on foreign currencies from sources outside of Japan. As a result, fluctuations in foreign exchange rates, particularly of the U.S. dollar, beyond levels anticipated by us could have a material effect on our results of operations. In addition, because the financial statements of our foreign subsidiaries are denominated in foreign currencies, fluctuations in foreign currencies and their effects on the yen-equivalent amounts could have an impact on our financial condition and results of operations.

Costs related to our pension and retirement benefit plans may increase if the fair value of our pension plan assets declines or if there is a change in the actuarial assumptions on which the calculations of the retirement benefit obligation are based, which could have a material effect on our financial condition and results of operations.

# (16) We face risks related to strategic alliances

From time to time, we enter into various alliances with third parties in connection with research and development, manufacturing and sales activities. If the business environment changes after entering into an alliance or for other reasons, the alliances may not have the effect that we originally anticipated. In addition, to the extent that we are subject to non-compete obligations with respect to a particular region, time period or product, our financial condition and results of operations could be



materially and adversely affected.

Currently, a patent infringement action has been filed against a number of generic companies for the product *SPRYCEL*, whose patent is held by BMS and is being co-developed and co-marketed by us. Any unfavorable ruling, decision or settlement resulting in the launch of generic versions of *SPRYCEL* in the U.S. could have a material adverse effect on our financial condition and results of operations.

# (17) We are subject to risks related to the operation of businesses in foreign countries

Outside of Japan, we conduct business operations mainly in the U.S., Europe and Asia, including research and development, manufacturing and sales activities. We are thus subject to risks related to maintaining global operations, including risks related to foreign laws and regulations, economic environment, political instability and uncertain business environment. If any of the events listed above or other similar events in relation to our international operations should occur, our business, results of operations and financial condition could be adversely affected.

# (18) We may be subject to liability and regulatory action if we are unable to protect personal and other confidential information

In connection with our internet sales of nutraceuticals and consumer products, we hold various information on individual customers that is considered personal information under the Law Concerning Protection of Personal Information of Japan (Law No. 57 of 2003, as amended), a law generally designed to protect the personal information of individuals. Under such law, relevant authorities may issue recommendations or orders against us if we fail to protect the personal information of our customers, and we may be required to provide compensation for economic loss and emotional distress arising out of a failure to protect personal information in accordance with this law. In addition, incidents of mishandling of personal information could create a negative public perception of our operations, which may in turn lead to reduced sales or otherwise materially and adversely affect our business, financial condition and results of operations.

# Consolidated Balance Sheet

ACCETC	Millions	of Yen	Thousands of U.S. Dollars (Note 1)		
ASSETS	2012.3	2011.3	2012.3		
Current assets:					
Cash and cash equivalents (Notes 10 and 21)	¥ 384,194	¥ 387,326	\$ 4,674,462		
Time deposits (Note 21)	142,570	91,195	1,734,639		
Marketable securities (Notes 7 and 21)	36,597	31,535	445,273		
Receivables (Notes 10 and 21):					
Trade notes	12,226	11,691	148,753		
Trade accounts	249,325	226,444	3,033,520		
Unconsolidated subsidiaries and affiliated companies	3,445	1,812	41,915		
Other	15,247	15,098	185,509		
Allowance for doubtful receivables	(390)	(350)	(4,745)		
Inventories (Notes 8 and 10)	119,367	114,899	1,452,330		
Deferred tax assets (Note 14)	34,342	24,580	417,837		
Other current assets	15,376	17,000	187,079		
Total current assets	1,012,299	921,230	12,316,572		
Property, plant, and equipment (Notes 9 and 10):  Land	74,926	74,926	911,619		
Buildings and structures	284,169	280,700	3,457,464		
Machinery and equipment	283,583	276,333	3,450,335		
Furniture and fixtures	72,269	69,018	879,292		
Lease assets	17,610	18,252	214,260		
Construction in progress	11,389	6,321	138,569		
Total property, plant, and equipment	743,946	725,550	9,051,539		
Accumulated depreciation	(488,431)	(468,717)	(5,942,706)		
Net property, plant, and equipment	255,515	256,833	3,108,833		
	· · · · · · · · · · · · · · · · · · ·				
nvestments and other assets:					
Investment securities (Notes 7 and 21)	108,351	103,169	1,318,299		
Investments in and advances to unconsolidated subsidiaries and affiliated companies (Note 21)	181,614	177,516	2,209,685		
Goodwill (Note 9)	36,825	41,445	448,047		
Intangible assets (Note 9)	30,297	35,643	368,621		
Deferred tax assets (Note 14)	25,347	32,245	308,395		
Other assets	16,519	21,636	200,986		
Total investments and other assets	398,953	411,654	4,854,033		
Total	¥1,666,767	¥1,589,717	\$20,279,438		

The accompanying notes are an integral part of these statements.

LIADULTIES AND FOUTY	Millions	Millions of Yen				
LIABILITIES AND EQUITY	2012.3	2011.3	(Note 1) <b>2012.3</b>			
Current liabilities:						
Short-term borrowings (Notes 10 and 21)	¥ 34,668	¥ 29,683	\$ 421,803			
Current portion of long-term debt (Notes 10 and 21)	7,998	26,894	97,311			
Payables (Note 21):						
Trade notes	8,524	7,533	103,711			
Trade accounts	84,630	78,853	1,029,687			
Construction	6,690	5,379	81,397			
Unconsolidated subsidiaries and affiliated companies	3,259	3,202	39,652			
Other	42,219	38,766	513,676			
Income taxes payable (Note 21)	33,823	13,301	411,522			
Accrued expenses	50,487	50,675	614,272			
Provision for loss on business liquidation (Note 18)	2,186	_	26,597			
Other current liabilities	36,875	21,272	448,655			
Total current liabilities	311,359	275,558	3,788,283			
Total current numinics	311,333	213,330	5,700,203			
Long-term liabilities:						
Long-term debt (Note 10)	31,735	35,826	386,118			
Liability for employees' retirement benefits (Note 11)	44,709	44,334	543,971			
Retirement benefits for directors and corporate auditors	3,091	3,417	37,608			
Negative goodwill	26,469	28,933	322,046			
Long-term unearned revenues (Note 23)	15,253	22,575	185,582			
Deferred tax liabilities (Note 14)	7,983	10,796	97,129			
Other long-term liabilities	3,403	4,952	41,404			
Total long-term liabilities	132,643	150,833	1,613,858			
Commitments and contingent liabilities (Notes 19, 22, and 23)						
<b>Equity</b> (Notes 12, 13, and 27):						
Common stock:	81,691	81,691	993,929			
Authorized — 1,600,000,000 shares in 2012 and 2011 Issued — 557,835,617 shares in 2012 and 2011		- 1,	,			
Capital surplus	510,639	510,639	6,212,909			
Stock acquisition rights	1,134	465	13,797			
Retained earnings	675,411	609,967	8,217,679			
Treasury stock, at cost:	(8)	(4)	(98)			
,	(0)	(4)	(50)			
3,978 shares in 2012 2,044 shares in 2011						
Accumulated other comprehensive income:						
Unrealized gain on available-for-sale securities	750	359	9,125			
Deferred gain (loss) on derivatives under hedge accounting	11	(4)	134			
Foreign currency translation adjustments	(59,905)	(52,446)	(728,860)			
Total	(59,144)	(52,091)	(719,601)			
Minority interests	13,042	12,659	158,682			
Total equity	1,222,765	1,163,326	14,877,297			
Total	¥1,666,767	¥1,589,717	\$20,279,438			

The accompanying notes are an integral part of these statements.

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries for the year ended March 31, 2012

	Millions	Thousands of U.S. Dollars (Note 1)	
	2012.3	2011.3	2012.3
Net sales (Notes 4 and 15)	¥1,154,574	¥1,127,589	\$14,047,621
Cost of sales	389,263	379,025	4,736,136
Gross profit	765,311	748,564	9,311,485
Selling, general, and administrative expenses (Note 16)	616,649	622,272	7,502,725
Operating income	148,662	126,292	1,808,760
Other income (expenses):			
Interest and dividend income	2,803	2,541	34,104
Interest expense	(1,702)	(1,541)	(20,708)
Foreign exchange loss, net	(2,712)	(5,742)	(32,997)
Amortization of negative goodwill	2,465	2,496	29,992
Equity in earnings of unconsolidated subsidiaries and affiliated companies	1,216	3,711	14,795
Loss on impairment of long-lived assets (Note 9)	(2,685)	(2,758)	(32,668)
Loss on valuation of investment securities and investments in	(·)	( ·)	
unconsolidated subsidiaries and affiliated companies	(3,665)	(2,534)	(44,592)
Gain on change in equity interest	322	5,571	3,918
Disaster-related loss (Note 17)	(267)	(1,841)	(3,249)
Gain on reversal of disaster-related loss	580	_	7,057
Loss on transfer of business (Note 25)	(684)	(1,901)	(8,322)
IPO expenses	_	(777)	_
Provision for loss on business liquidation (Note 18)	(2,186)	_	(26,597)
Other, net	258	(487)	3,139
Other expenses, net	(6,257)	(3,262)	(76,128)
Income before income taxes and minority interests	142,405	123,030	1,732,632
Income taxes (Note 14):			
Current	54,989	33,599	669,047
Deferred	(5,397)	5,438	(65,665)
Total income taxes	49,592	39,037	603,382
Net income before minority interests	92,813	83,993	1,129,250
Minority interests in net income	639	1,623	7,775
Net income	¥ 92,174	¥ 82,370	\$ 1,121,475

		U.S. Dollars	
	2012.3	2011.3	2012.3
Per share of common stock (Notes 2(t) and 26):			
Basic net income	¥165.20	¥164.52	\$2.01
Diluted net income	164.73	164.40	2.00
Cash dividends applicable to the year	45.00	28.00	0.55

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Comprehensive Income

Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries for the year ended March 31, 2012

	Millions	Thousands of U.S. Dollars (Note 1)	
	2012.3	2011.3	2012.3
Net income before minority interests	¥ 92,813	¥83,993	\$1,129,250
Other comprehensive income (loss) (Note 24):			
Unrealized gain (loss) on available-for-sale securities	300	(3,851)	3,650
Deferred gain on derivatives under hedge accounting	15	11	183
Foreign currency translation adjustments	(4,891)	(10,364)	(59,509)
Share of other comprehensive income in affiliated companies	(3,024)	(9,853)	(36,793)
Total other comprehensive loss	(7,600)	(24,057)	(92,469)
Comprehensive income (Note 24)	¥ 85,213	¥ 59,936	\$1,036,781
Total comprehensive income attributable to (Note 24):			
Owners of the parent	¥ 85,141	¥ 58,980	\$1,035,905
Minority interests	72	956	876

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Changes in Equity

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries for the year ended March 31, 2012

	Thousands						Millions of Yer	า				
		Accumulated other comprehensive incom			ensive income							
	Outstanding number of shares of common stock	Common stock	Capital surplus	Stock acquisition rights	Retained earnings	Treasury stock	Unrealized gain (loss) on available- for-sale securities	Deferred (loss) gain on derivatives under hedge accounting	Foreign currency translation adjustments	Total	Minority interests	Total equity
Balance, April 1, 2010	476,547	¥ 42,946	¥432,482	¥ —	¥532,032	¥ (45,354)	¥4,259	¥ (15)	¥ (30,060)	¥ 936,290	¥12,167	¥ 948,457
Cumulative effect of change in accounting policies					2,716				(2,716)	_		_
Balance, April 1, 2010, as restated	476,547	¥ 42,946	¥432,482	_	¥534,748	¥ (45,354)	¥4,259	¥ (15)	¥ (32,776)	¥ 936,290	¥12,167	¥ 948,457
Cash dividends, ¥12.5 per share					(5,957)					(5,957)		(5,957)
Issuance of new shares (Note 12)	38,679	38,745	38,745							77,490		77,490
Net income					82,370					82,370		82,370
Disposal of treasury stock	42,610		39,412			45,354				84,766		84,766
Purchase of treasury stock	(2)					(4)				(4)		(4)
Adjustment of retained earnings for newly consolidated subsidiaries and affiliated companies (Note 2(a))					(1,194)					(1,194)		(1,194)
Net change in the year				465			(3,900)	11	(19,670)	(23,094)	492	(22,602)
Balance, March 31, 2011	557,834	¥81,691	¥510,639	¥ 465	¥609,967	¥ (4)	¥ 359	¥ (4)	¥ (52,446)	¥1,150,667	¥12,659	¥1,163,326
Cash dividends, ¥48 per share					(26,776)					(26,776)		(26,776)
Issuance of new shares (Note 12)										_		_
Net income					92,174					92,174		92,174
Disposal of treasury stock										_		_
Purchase of treasury stock	(2)					(4)				(4)		(4)
Adjustment of retained earnings for newly consolidated subsidiary and affiliated company (Note 2(a))					46					46		46
Net change in the year				669			391	15	(7,459)	(6,384)	383	(6,001)
Balance, March 31, 2012	557,832	¥81,691	¥510,639	¥1,134	¥675,411	¥ (8)	¥ 750	¥ 11	¥ (59,905)	¥1,209,723	¥13,042	¥1,222,765

The accompanying notes are an integral part of these statements.

	Thousands of U.S. Dollars (Note 1)										
	Accumulated other comprehensive income										
	Common stock	Capital surplus	Stock acquisition rights	Retained earnings	Treasury stock	Unrealized gain on available- for-sale securities	Deferred (loss) gain on derivatives under hedge accounting	Foreign currency translation adjustments	Total	Minority Interests	Total equity
Balance, March 31, 2011	\$ 993,929	\$6,212,909	\$ 5,658	\$7,421,426	\$ (49)	\$4,368	\$ (49)	\$ (638,107)	\$14,000,085	\$154,021	\$14,154,106
Cash dividends, \$0.58 per share				(325,782)					(325,782)		(325,782)
Issuance of new shares (Note 12)									_		_
Net income				1,121,475					1,121,475		1,121,475
Disposal of treasury stock									_		_
Purchase of treasury stock					(49)				(49)		(49)
Adjustment of retained earnings for newly consolidated subsidiary and affiliated company (Note 2(a))				560					560		560
Net change in the year			8,139			4,757	183	(90,753)	(77,674)	4,661	(73,013)
Balance, March 31, 2012	\$ 993,929	\$6,212,909	\$13,797	\$8,217,679	\$ (98)	\$9,125	\$134	\$ (728,860)	\$14,718,615	\$158,682	\$14,877,297

The accompanying notes are an integral part of these statements.

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries for the year ended March 31, 2012

	Millions	Thousands of U.S. Dollars (Note 1)	
	2012.3	2011.3	2012.3
Operating activities:			
Income before income taxes and minority interests	¥ 142,405	¥123,030	\$1,732,632
Adjustments for:			
Income taxes paid	(34,422)	(59,942)	(418,810)
Depreciation and amortization	48,062	48,097	584,767
Amortization of negative goodwill	(2,465)	(2,496)	(29,992)
Equity in earnings of unconsolidated subsidiaries and affiliated			
companies	(1,216)	(3,711)	(14,795)
Gain on change in equity interest	(322)	(5,571)	(3,918)
Provision for loss on business liquidation	2,186	4 004	26,597
Loss on transfer of business	684	1,901	8,322
Loss on impairment of long-lived assets	2,685	2,758	32,668
Loss on valuation of investment securities and investments in unconsolidated subsidiaries and affiliated companies	3,665	2,534	44,592
Changes in assets and liabilities:			
Increase in trade receivables	(25,658)	(17,004)	(312,179)
Increase in inventories	(7,412)	(7,376)	(90,181)
Increase in trade payables	8,473	2,095	103,090
Decrease in long-term unearned revenues	(7,322)	(7,322)	(89,086)
Other, net	18,276	10,754	222,363
Net cash provided by operating activities	147,619	87,747	1,796,070
Investing activities:			
Increase in short-term investment securities	(6,954)	_	(84,609)
Proceeds from sales of property, plant, and equipment	681	507	8,286
Purchases of property, plant, and equipment	(36,034)	(35,409)	(438,423)
Proceeds from sales and redemptions of investment securities	17,435	27,732	212,130
Proceeds from transfer of business (Note 25)	1,382	2,100	16,815
Payments for transfer of business (Note 25)	(1,278)	_	(15,549)
Purchases of investment securities	(21,060)	(31,504)	(256,236)
Purchases of stock of unconsolidated subsidiaries and affiliated companies	(10,655)	(3,516)	(129,639)
Increase in time deposits (Note 4)	(47,504)	(85,757)	(577,978)
Other, net	(3,642)	(5,662)	(44,312)
Net cash used in investing activities	(107,629)	(131,509)	(1,309,515)
Financing activities:	, , ,		· · · · · ·
Increase (decrease) in short-term debt	3,194	(6,708)	38,861
Proceeds from long-term debt	2,295	2,567	27,923
Repayments of long-term debt	(23,834)	(33,774)	(289,987)
Issuance of common stock	_	77,490	(200)0017
Proceeds from disposal of treasury stock	_	85,246	_
Dividends paid	(26,776)	(5,958)	(325,782)
Dividends paid to minority interests in consolidated subsidiaries	(404)	(359)	(4,915)
Other, net	4,460	(4,937)	54,265
Net cash (used in) provided by financing activities	(41,065)	113,567	(499,635)
Foreign currency translation adjustments on cash and cash	(+1,003)	113,307	(433,033)
equivalents	(1,362)	(5,323)	(16,571)
Net (decrease) increase in cash and cash equivalents	(2,437)	64,482	(29,651)
Cash and cash equivalents of newly consolidated subsidiaries	(695)	1,538	(8,456)
Cash and cash equivalents, beginning of year	387,326	321,306	4,712,569
Cash and cash equivalents, end of year	¥ 384,194	¥ 387,326	\$4,674,462

The accompanying notes are an integral part of these statements.

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries

# 1. Basis of presenting consolidated financial statements

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which differ in certain respects from the application and disclosure requirements of accounting principles generally accepted in the United States of America ("U.S. GAAP") and the International Financial Reporting Standards.

In preparing these consolidated financial statements, certain reclassifications and presentational changes have been made to the consolidated financial statements issued domestically in order to present them in a form, which is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2011 consolidated financial statements to conform to the classifications used in 2012.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Otsuka Holdings Co., Ltd. (the "Company"), is incorporated and operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥82.19 to \$1, the approximate rate of exchange at March 31, 2012. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

# 2. Summary of significant accounting policies

# (a) Consolidation

The consolidated financial statements as of March 31, 2012 include the accounts of the Company and its 67 significant (69 as of March 31, 2011) subsidiaries (together, the "Group"). Under the control or influence concept, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Group has the ability to exercise significant influence are accounted for by the equity method.

Investments in one (one as of March 31, 2011) unconsolidated subsidiary and 12 (11 as of March 31, 2011) affiliated companies are accounted for by the equity method.

During the year ended March 31, 2012, one subsidiary was newly included in the consolidated financial statements due to the increase in materiality while two subsidiaries were absorbed by other consolidated subsidiaries and one subsidiary became the affiliated company accounted for by the equity method because the ownership share of the Group decreased due to the transfer of its equity shares.

Investments in the remaining unconsolidated subsidiaries and affiliated companies are stated at cost. If the equity method of accounting had been applied to the investments in these companies, the effect on the accompanying consolidated financial statements would not be material.

The excess of cost of investments in consolidated subsidiaries over fair value of their net assets or the excess of net assets of consolidated subsidiaries over purchase cost at the date of acquisition is amortized on a straight-line basis over a period of five or 20 years.

All significant intercompany balances and transactions have been eliminated in consolidation. All material unrealized profit included in assets resulting from transactions within the Group has also been eliminated.

# (b) Unification of accounting policies applied to foreign subsidiaries for the consolidated financial statements

In May 2006, the Accounting Standards Board of Japan (ASBJ) issued ASBJ Practical Issues Task Force (PITF) No. 18, "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for the Consolidated Financial Statements." PITF No. 18 prescribes:

- (1) The accounting policies and procedures applied to a parent company and its subsidiaries for similar transactions and events under similar circumstances should in principle be unified for the preparation of the consolidated financial statements.
- (2) Financial statements prepared by foreign subsidiaries in accordance with either International Financial Reporting Standards or U.S. GAAP tentatively may be used for the consolidation process.
- (3) However, the following items should be adjusted in the consolidation process so that net income is accounted for in accordance with Japanese GAAP, unless they are not material:
  - 1) Amortization of goodwill
  - 2) Scheduled amortization of actuarial gain or loss of pensions that has been directly recorded in equity
  - 3) Expensing capitalized development costs of R&D
  - Cancellation of the fair value model accounting for property, plant, and equipment and investment properties and incorporation of the cost model accounting
  - 5) Exclusion of minority interests from net income, if contained

# (c) Unification of accounting policies applied to foreign associated companies for the equity method

In March 2008, the ASBJ issued ASBJ Statement No. 16, "Accounting Standard for Equity Method of Accounting for Investments." The new standard requires adjustments to be made to conform the associate's accounting policies for similar transactions and events under similar circumstances to those of the parent company when the associate's financial statements are used in applying the equity method, unless it is impracticable to determine adjustments. In addition, financial statements prepared by foreign associated companies in accordance with either International Financial Reporting Standards or the U.S. GAAP tentatively may be used in applying the equity method if the following items are adjusted so that net income is accounted for in accordance with Japanese GAAP, unless they are not material:

- (1) Amortization of goodwill
- (2) Scheduled amortization of actuarial gain or loss of pensions that has been directly recorded in the equity
- (3) Expensing capitalized development costs of R&D
- (4) Cancellation of the fair value model accounting for property, plant, and equipment and investment properties and incorporation of the cost model accounting
- (5) Exclusion of minority interests from net income, if contained

## (d) Business combination

In October 2003, the Business Accounting Council issued a Statement of Opinion, "Accounting for Business Combinations," and in December 2005, the ASBJ issued ASBJ Statement No. 7, "Accounting Standard for Business Divestitures," and ASBJ Guidance No. 10, "Guidance for Accounting Standard for Business Combinations and Business Divestitures."

The accounting standard for business combinations allows companies to apply the pooling of interests method of accounting only when certain specific

criteria are met such that the business combination is essentially regarded as a uniting of interests.

For business combinations that do not meet the uniting-of-interests criteria, the business combination is considered to be an acquisition and the purchase method of accounting is required. This standard also prescribes the accounting for combinations of entities under common control and for joint ventures.

In December 2008, the ASBJ issued a revised accounting standard for business combinations, ASBJ Statement No. 21, "Accounting Standard for Business Combinations." Major accounting changes under the revised accounting standard are as follows:

- (1) The revised standard requires accounting for business combinations only by the purchase method. As a result, the pooling of interests method of accounting is no longer allowed.
- (2) The current accounting standard accounts for the research and development costs to be charged to income as incurred. Under the revised standard, in-process research and development acquired in the business combination is capitalized as an intangible asset.
- (3) The previous accounting standard provided for a bargain purchase gain (negative goodwill) to be systematically amortized over a period not exceeding 20 years. Under the revised standard, the acquirer recognizes the bargain purchase gain in profit or loss immediately on the acquisition date after reassessing and confirming that all of the assets acquired and all of the liabilities assumed have been identified after a review of the procedures used in the purchase allocation.

### (e) Cash equivalents

Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value. Cash equivalents include time deposits and certificate of deposits, all of which mature or become due within three months of the date of acquisition.

## (f) Securities

Securities other than equity securities issued by subsidiaries and affiliated companies are classified into held-to-maturity and available-for-sale securities. Held-to-maturity securities are carried at amortized cost. Marketable securities classified as available-for-sale securities are carried at fair value with unrealized gains or losses, net of applicable taxes, stated in a separate component of equity.

Nonmarketable securities classified as available-for-sale securities are stated at cost as determined by the moving-average method.

For other-than-temporary declines in fair value, investment securities are reduced to net realizable value by a charge to income.

#### (g) Inventories

Inventories are stated at the lower of cost, determined mainly by the average method for finished products, work in process, and raw materials and mainly by the first-in, first-out method for merchandise and supplies, or net selling value.

## (h) Property, plant, and equipment

Property, plant, and equipment are stated at cost. Depreciation of property, plant, and equipment of the Company and its consolidated domestic subsidiaries is computed principally by the declining-balance method over the estimated useful lives of the assets, while the straight-line method is applied to buildings acquired after April 1, 1998.

Consolidated foreign subsidiaries mainly compute depreciation by the straight-line method.

The range of useful lives is from three to 65 years for buildings and structures and from two to 25 years for machinery and equipment.

Lease assets are depreciated using the straight-line method over the terms of their respective leases with a zero residual value.

## (i) Intangible assets

Intangible assets are amortized mainly by the straight-line method over their estimated useful lives.

### (j) Long-lived assets

The Group reviews its long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss is measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from continued use and eventual disposition of the asset or the current net selling price at disposition.

#### (k) Retirement benefits

Certain domestic consolidated subsidiaries have adopted retirement benefit plans consisting of lump-sum retirement payments, defined pension plans, and defined contribution pension plans. Certain foreign consolidated subsidiaries have adopted defined benefit pension plans or defined contribution pension plans, or a combination of the two.

Provisions have been made for employees' retirement benefits, based on an estimate of the projected retirement benefit obligation and the fair value of the pension fund assets.

Retirement benefits for directors and corporate auditors of certain domestic consolidated subsidiaries are recorded to state the liability at the amount that would be required if all directors and corporate auditors retired at the balance sheet date. These amounts are paid only after an approval of the shareholders' meeting in accordance with the Companies Act of Japan (the "Companies Act").

## (I) Asset retirement obligations

In March 2008, the ASBJ published the accounting standard for asset retirement obligations, ASBJ Statement No. 18, "Accounting Standard for Asset Retirement Obligations," and ASBJ Guidance No. 21, "Guidance on Accounting Standard for Asset Retirement Obligations." Under this accounting standard, an asset retirement obligation is defined as a legal obligation imposed either by law or contract that results from the acquisition, construction, development, and the normal operation of a tangible fixed asset and is associated with the retirement of such tangible fixed asset. The asset retirement obligation is recognized as the sum of the discounted cash flows required for the future asset retirement and is recorded in the period in which the obligation is incurred if a reasonable estimate can be made. If a reasonable estimate of the asset retirement obligation cannot be made in the period the asset retirement obligation is incurred, the liability should be recognized when a reasonable estimate of asset retirement obligation can be made. Upon initial recognition of a liability for an asset retirement obligation, an asset retirement cost is capitalized by increasing the carrying amount of the related fixed asset by the amount of the liability. The asset retirement cost is subsequently allocated to expense through depreciation over the remaining useful life of the asset. Over time, the liability is accreted to its present value each period. Any subsequent revisions to the timing or the

# Notes to Consolidated Financial Statements

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries

amount of the original estimate of undiscounted cash flows are reflected as an increase or a decrease in the carrying amount of the liability and the capitalized amount of the related asset retirement cost.

### (m) Stock options

In December 2005, the ASBJ issued ASBJ Statement No. 8, "Accounting Standard for Stock Options," and related guidance. The new standard and guidance are applicable to stock options newly granted on and after May 1, 2006. This standard requires companies to recognize compensation expense for employee stock options based on the fair value at the date of grant and over the vesting period as consideration for receiving goods or services. The standard also requires companies to account for stock options granted to nonemployees based on the fair value of either the stock option or the goods or services received. In the balance sheet, the stock option is presented as a stock acquisition right as a separate component of equity until exercised. The standard covers equity-settled, share-based payment transactions, but does not cover cash-settled, share-based payment transactions. In addition, the standard allows unlisted companies to measure options at their intrinsic value if they cannot reliably estimate fair value.

## (n) Research and development expenses

Research and development expenses are charged to income as incurred.

#### (o) Leases

In March 2007, the ASBJ issued ASBJ Statement No. 13, "Accounting Standard for Lease Transactions," which revised the previous accounting standard for lease transactions issued in June 1993. The revised accounting standard for lease transactions is effective for fiscal years beginning on or after April 1, 2008.

Under the previous accounting standard, finance leases that were deemed to transfer ownership of the leased property to the lessee were required to be capitalized. However, other finance leases were permitted to be accounted for as operating lease transactions if certain "as if capitalized" information was disclosed in the notes to the lessee's financial statements. The revised accounting standard requires that all finance lease transactions be capitalized to recognize lease assets and lease obligations in the balance sheet.

The Company applied the revised accounting standard, effective April 1, 2008. In addition, the Company accounted for leases which existed at the transition date and do not transfer ownership of the leased property to the lessee as if such leased assets had been acquired at the transition date at costs measured at the obligations under the finance leases. This change had no effect on the consolidated results of the Company.

All other leases are accounted for as operating leases.

# (p) Income taxes

The provision for income taxes is computed based on the pretax income included in the consolidated statements of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. Deferred taxes are measured by applying currently enacted tax laws to the temporary differences.

### (q) Foreign currency transactions

All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates as of the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statements of income to the extent that they

are not hedged by forward exchange contracts.

#### (r) Foreign currency translation

The balance sheet accounts of the consolidated foreign subsidiaries are translated into Japanese yen at the current exchange rate as of the balance sheet date except for shareholders' equity, which is translated at the historical rate. Revenue and expense accounts of consolidated foreign subsidiaries are translated into yen at the average exchange rate.

Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity.

## (s) Derivative financial instruments

The Group uses foreign currency forward contracts, foreign currency option contracts, and interest rate swaps to reduce foreign currency exchange and interest rate risks. The Group does not enter into derivative transactions for trading or speculative purposes.

Derivative financial instruments and foreign currency transactions are classified and accounted for as follows:

- (1) All derivatives are recognized as either assets or liabilities and measured at fair value, with gains or losses recognized in the consolidated statements of income.
- (2) For derivatives used for hedging purposes, if derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until the related losses or gains on the hedged items are recognized.

If foreign currency forward contracts and foreign currency option contracts qualify for hedge accounting and meet specific matching criteria, assets and liabilities denominated in foreign currencies are translated at the contract rates and no gains or losses on derivative transactions are recognized.

Interest rate swaps, which qualify for hedge accounting and meet specific matching criteria, are not remeasured at market value, but the differential paid or received under the swap agreements is recognized as and included in interest expense or income.

## (t) Per share information

Basic net income per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding for the period.

Diluted net income per share reflects the potential dilution that could occur if stock options were exercised into common stock. Diluted net income per share of common stock assumes full exercise of outstanding stock options at the beginning of the year (or at the time of issuance).

Cash dividends per share presented in the accompanying consolidated statements of income are dividends applicable to the respective years, including dividends to be paid after the end of the year.

#### (u) Accounting Changes and Error Corrections

In December 2009, the ASBJ issued ASBJ Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections."

Accounting treatments under this standard and guidance are as follows:

(1) Changes in accounting policies

When a new accounting policy is applied with revision of accounting standards, a new policy is applied retrospectively, unless the revised accounting standards include specific transitional provisions. When the revised accounting standards include specific transitional provisions, an entity shall comply with the specific transitional provisions.

(2) Changes in presentation

When the presentation of financial statements is changed, priorperiod financial statements are reclassified in accordance with the new presentation.

(3) Changes in accounting estimates

A change in an accounting estimate is accounted for in the period of the change if the change affects that period only and is accounted for prospectively if the change affects both the period of the change and future periods.

(4) Corrections of prior-period errors

When an error in prior-period financial statements is discovered, those statements are restated.

This accounting standard and the guidance are applicable to accounting changes and corrections of prior-period errors, which are made from the beginning of the fiscal year that begins on or after April 1, 2011.

#### (v) New accounting pronouncements

Accounting Standard for Retirement Benefits—On May 17, 2012, the ASBJ issued ASBJ Statement No. 26, "Accounting Standard for Retirement Benefits," and ASBJ Guidance No. 25, "Guidance on Accounting Standard for Retirement Benefits," which replaced the Accounting Standard for Retirement Benefits that had been issued by the Business Accounting Council in 1998 with effective date of April 1, 2000 and the other related practical guidances, being followed by partial amendments from time to time through 2009.

Major changes are as follows:

(1) Treatment in the balance sheet

Under the current requirements, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss are not recognized in the balance sheet, and the difference between retirement benefit obligations and plan assets (hereinafter, "deficit or surplus"), adjusted by such unrecognized amounts, are recognized as a liability or asset.

Under the revised accounting standard, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss shall be recognized within equity (accumulated other comprehensive income), after adjusting for tax effects, and the deficit or surplus shall be recognized as a liability (liability for retirement benefits) or asset (asset for retirement benefits).

(2) Treatment in the statement of income and the statement of comprehensive income (or the statement of income and comprehensive income)

The revised accounting standard would not change how to recognize actuarial gains and losses and past service costs in profit or loss. Those amounts would be recognized in profit or loss over a certain period no longer than the expected average remaining working lives of the employees. However, actuarial gains and losses and past service costs that arose in the current period and yet to be recognized in profit or loss shall be included in other comprehensive income, and actuarial gains and losses and past service costs that were recognized in other

comprehensive income in prior periods and then recognized in profit or loss in the current period shall be treated as reclassification adjustments.

This accounting standard and the guidance are effective for the end of annual periods beginning on or after April 1, 2013 with earlier application being permitted from the beginning of annual periods beginning on or after April 1, 2013. However, no retrospective application of this accounting standard to consolidated financial statements in prior periods is required.

The Company expects to apply the revised accounting standard from the end of the annual period beginning on April 1, 2013 and is in the process of measuring the effects of applying the revised accounting standard for the year ending March 31, 2014.

# 3. Changes in accounting policies

 Change in the method of translating revenue and expense accounts of foreign subsidiaries and affiliated companies

Previously, revenue and expense accounts of foreign subsidiaries and affiliated companies were translated into Japanese yen at the current exchange rate as of the balance sheet date of such foreign subsidiaries and affiliated companies. From the current fiscal year, such accounts are translated at the average exchange rate for the year. The Group changed its method of translation to more accurately reflect the performances of foreign subsidiaries and affiliated companies in the consolidated financial statements by mitigating the effects of temporary fluctuations in exchange rates and taking into consideration importance of foreign subsidiaries and affiliated companies.

The prior-year consolidated financial statements for the full year have been adjusted retrospectively to apply the change in accounting policy.

The major effects of the changes in accounting policies (mentioned above) and method of presentation (mentioned in "4. Changes in Method of Presentation") on the prior-period consolidated financial statements were as follows. The cumulative effect on prior year's beginning equity balance increased retained earnings by ¥2,716 million and decreased foreign currency translation adjustments by the same amount.

The effects of the change in translation method on per share information are presented in Note 26.

### 1) Consolidated Balance Sheet

As of March 31, 2011

	Millions of Yen									
		Before trospective djustment		After trospective djustment	Diffe	Difference		Effect of in trans meth	lation	
ASSETS										
Current assets:										
Receivable-trade accounts	¥	226,350	¥	226,444	¥		94	¥	94	
Inventories		114,863		114,899			36		36	
Deferred tax assets		24,633		24,580			(53)		(53)	
Total current assets		921,153		921,230			77		77	
Total assets	¥	1,589,640	¥	1,589,717	¥		77	¥	77	
EQUITY										
Retained earnings	¥	605,883	¥	609,967	¥	4,0	084	¥	4,084	
Accumulated other comprehensive income:										
Foreign currency translation adjustments		(48,439)		(52,446)		(4,0	007)	(	4,007)	
Total accumulated other comprehensive income		(48,084)		(52,091)		(4,0	007)	(-	4,007)	
Total equity	1	1,163,249	1	1,163,326			77		77	
Total liabilities and equity	¥	1,589,640	¥ ′	1,589,717	¥		77	¥	77	

# Notes to Consolidated Financial Statements

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries

#### 2) Consolidated Statement of Income

From April 1, 2010 to March 31, 2011

				Millions of Yen			
	Before retrospective adjustment and reclassification	adju	After rospective stment and assification	Difference	Effect of change in translation method	Effect of chang in presentatio method	
Net sales	¥1,090,213	¥1	,127,589	¥ 37,376	¥ 30,053	¥ 7,32	3
Cost of sales	367,092		379,025	11,933	11,933	_	-
Gross profit	723,121		748,564	25,443	18,120	7,32	3
Selling, general, and administrative expenses	605,618		622,272	16,654	16,654	_	_
Operating income	117,503		126,292	8,789	1,466	7,32	3
Other income (expense), net	3,772		(3,262)	(7,034)	289	(7,32	3)
Income before income taxes and minority interests	121,275		123,030	1,755	1,755	_	_
Income taxes:							
Current	33,198		33,599	401	401	_	_
Deferred	5,511		5,438	(73)	(73)	_	-
Total income taxes	38,709		39,037	328	328	_	_
Net income before minority interests	82,566		83,993	1,427	1,427	_	_
Minority interests in net income	1,564		1,623	59	59	_	_
Net income	¥ 81,002	¥	82,370	¥ 1,368	¥ 1,368	¥ -	Ξ

#### 3) Consolidated Statement of Changes in Equity

From April 1, 2010 to March 31, 2011

		Millions	of Yen	
	Before retrospective adjustment	After retrospective adjustment	Difference	Effect of change in translation method
Retained earnings				
Balance, April 1, 2010	¥ 532,032	¥ 532,032	¥ —	¥ —
Cumulative effect of changes in accounting policies	_	2,716	2,716	2,716
Balance, April 1, 2010, as restated	532,032	534,748	2,716	2,716
Changes during the year:				
Net income	81,002	82,370	1,368	1,368
Total changes during the year	73,851	75,219	1,368	1,368
Balance, March 31, 2011	605,883	609,967	4,084	4,084
Foreign currency translation adjustments Balance, April 1, 2010	(30,060)	(30,060)	_	_
Cumulative effect of changes in accounting policies	_	(2,716)	(2,716)	(2,716)
Balance, April 1, 2010, as restated	(30,060)	(32,776)	(2,716)	(2,716)
Changes during the year:				
Net change in the year	(18,379)	(19,670)	(1,291)	(1,291)
Total changes during the year	(18,379)	(19,670)	(1,291)	(1,291)
Balance, March 31, 2011	(48,439)	(52,446)	(4,007)	(4,007)
Total equity				
Balance, April 1, 2010	948,457	948,457	_	_
Cumulative effect of changes in accounting policies	_	_	_	_
Balance, April 1, 2010, as restated	948,457	948,457	_	_
Changes during the year:				
Net income	81,002	82,370	1,368	1,368
Net change in the year	(21,311)	(22,602)	(1,291)	(1,291)
Total changes during the year	214,792	214,869	77	77
Balance, March 31, 2011	¥1,163,249	¥1,163,326	¥ 77	¥ 77

# 4) Consolidated Statement of Cash Flows

From April 1, 2010 to March 31, 2011

	Millions of Yen			
	Before retrospective adjustment	After retrospective adjustment	Difference	Effect of change in translation method
Net cash provided by operating activities	¥ 86,394	¥ 87,747	¥1,353	¥1,353
Net cash used in investing activities	(130,878)	(131,509)	(631)	(631)
Net cash provided by financing activities	113,655	113,567	(88)	(88)
Foreign currency translation adjustments on cash and cash equivalents	(4,689)	(5,323)	(634)	(634)
Net increase in cash and cash equivalents	64,482	64,482	_	
Cash and cash equivalents, beginning of year	321,306	321,306	_	
Cash and cash equivalents of newly consolidated subsidiaries	1,538	1,538	_	_
Cash and cash equivalents, end of year	¥387,326	¥ 387,326	¥ —	¥ —

## 2. Application of accounting standard for earnings per share

Effective from current fiscal year, the Company applied "Accounting Standard for Earnings Per Share" (ASBJ Statement No. 2 revised on June 30, 2010), "Guidance on Accounting Standard for Earnings Per Share" (ASBJ Guidance No. 4 revised on June 30, 2010), and "Practical Solution on Accounting for Earnings Per Share" (ASBJ PITF No. 9 revised on June 30, 2010).

The effects of the change in translation method on per share information are presented in Note 26.

# 4. Changes in method of presentation

(Change in the method of presentation for up-front licensing payments received) Previously, up-front licensing payments received were recorded as "revenues related to extension of co-promotion agreement" and "other" included in other income. However, as such income is directly attributable to the core business activities in the pharmaceutical business and as such transactions are likely to grow in importance, the Group has changed its method of presentation to include such income as net sales from the current fiscal year.

Net sales recognized in the previous fiscal year as revenue from the up-front licensing payments received were ¥7,323 million.

(Change in the method of presentation for a component of cash flows from investing activities)

Previously, proceeds from withdrawal of time deposits and payment into time deposits were stated separately in investing activities of consolidated statements of cash flows. However, from the current year, the Group has changed the method of presentation to state net amount of these items as increase or decrease in time deposits. As a result of the change, in the consolidated statement of cash flows for the prior fiscal year, ¥(97,323) million and ¥11,566 million, proceeds from withdrawal of time deposits and payment into time deposits, respectively, were reclassified into ¥(85,757) million of increase in time deposits, net.

# 5. Additional information

#### Accounting method for employee shareholding incentive plan

The Company has adopted a "Trust-type Employee Shareholding Incentive Plan (E-Ship)" (the "Plan") in order to provide an enhanced benefits package and an incentive to increase the long-term enterprise value for the Group's employees.

Under the Plan, the "Employee Stock Holding Trust" (the "Trust") acquires the Company shares expected to be purchased by the "Otsuka Group Employee Stock Holding Plan" in the five-year period from July 2008 through a third-party allocation of new shares by the Company. Until termination, the Trust is responsible for transferring shares to the Employee Stock Holding Plan and receives dividends from the Company. If any money remains within the Trust, such money will be distributed as residual assets to those employees that fulfill the requirements for eligible beneficiaries.

The Company guaranteed the Trust's borrowings from financial institutions for the acquisition of Company shares. The Trust has repaid all of the borrowings as of March 31, 2011.

The Company does not recognize the Company shares owned by the Trust on its balance sheet as treasury stock and increased its common stock and additional paid-in capital (a component of capital surplus) at the time of the third-party allocation of new shares.

All of the Company shares owned by the Trust were sold at the end of the current fiscal year, and the beneficiaries to receive the equivalent amount of

surplus have been determined.

In addition, as of March 31, 2012, the Company had temporary custody of the residual assets (¥7,389 million) to be distributed to the beneficiaries, and this was included in the Company's other current liabilities.

## 6. Business combination

There were no material business combinations for the years ended March 31, 2012 and 2011.

## 7. Securities

Securities as of March 31, 2012 and 2011 consisted of the following:

	Millions	Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Current:			
Government and corporate bonds	¥ 36,596	¥ 31,394	\$ 445,261
Other	1	141	12
Total current	¥ 36,597	¥ 31,535	\$ 445,273
Noncurrent:			
Marketable equity securities	¥ 42,719	¥ 40,482	\$ 519,759
Government and corporate bonds	54,022	51,107	657,282
Other	11,610	11,580	141,258
Total noncurrent	¥108,351	¥103,169	\$1,318,299

The costs and aggregate fair values of marketable and investment securities at March 31, 2012 and 2011 were as follows:

	Millions of Yen				
March 31, 2012	Cost Unrealized Gains		Unrealized Losses	Fair Value	
Securities classified as:					
Available for sale:					
Equity securities	¥39,721	¥8,436	¥5,438	¥42,719	
Other	_	_	_	_	
Held to maturity	90,618	557	103	91,072	

		Millions of Yen				
March 31, 2011	Cost	Unrealized Gains	Unrealized Losses	Fair Value		
Securities classified as:	_					
Available for sale:						
Equity securities	¥37,636	¥ 7,314	¥ 4,468	¥40,482		
Other	140	_	_	140		
Held to maturity	82,501	681	191	82,991		

		Thousands of U.S. Dollars				
March 31, 2012		Cost Unrealized Gains		Fair Value		
Securities classified as:						
Available for sale:						
Equity securities	\$ 483,283	\$102,640	\$66,164	\$ 519,759		
Other	_	_	_	_		
Held to maturity	1,102,543	6,777	1,253	1,108,067		

Available-for-sale securities and held-to-maturity securities whose fair values are not determinable are disclosed in Note 21(4)(b).

The information of available-for-sale securities, which were sold during the years ended March 31, 2012 and 2011 were as follows:

•						
March 31, 2012		Millions of Yen				
Walti 31, 2012	Proceeds	Realized Gains	Realized Losses			
Available for sale:						
Equity securities	¥26	¥11	¥—			
Total	¥26	¥11	¥—			
May-b 24, 2011		Millions of Yen				
March 31, 2011	Proceeds	Realized Gains	Realized Losses			
Available for sale:						
Equity securities	¥13	¥—	¥1			
Total	¥13	¥—	¥1			

March 31, 2012	Thousands of U.S. Dollars				
March 31, 2012	Proceeds Realized Gains Realized L				
Available for sale:					
Equity securities	\$316	\$134	\$—		
Total	\$316	\$134	\$—		

The impairment losses on equity securities for the years ended March 31, 2012 and 2011 were  $\pm$ 3,665 million ( $\pm$ 44,592 thousand) and  $\pm$ 1,901 million, respectively.

## 8. Inventories

Inventories at March 31, 2012 and 2011 consisted of the following:

	Million	Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Finished products and merchandise	¥ 60,778	¥ 62,336	\$ 739,482
Work in process	26,932	23,614	327,680
Raw materials and supplies	31,657	28,949	385,168
Total	¥119,367	¥114,899	\$1,452,330

# 9. Long-lived assets

The Group reviewed its long-lived assets for impairment as of March 31, 2012. As a result, the Group recognized an impairment loss of ¥2,685 million (\$32,668 thousand) for certain intangible assets and business properties related to Nutraceuticals due to decline in profitability of this segment, for certain business properties related to Pharmaceuticals and Other due to low capacity utilization, and for certain idle assets due to substantial decline in their fair market value. The carrying amounts of these assets were written down to the recoverable amount.

Impairment losses, which the Group recognized for the years ended March 31, 2012 and 2011, were as follows:

Pharmaceuticals:	Million	Thousands of U.S. Dollars	
i narmaceuticais.	2012.3	2011.3	2012.3
Machinery and equipment	¥ 6	¥ —	\$ 73
Buildings and structures	645	_	7,847
Total	¥651	¥ —	\$ 7,920

Nutraceuticals:	Million	Thousands of U.S. Dollars	
wattaceuticais.	2012.3	2011.3	2012.3
Intangible assets	¥302	¥1,602	\$ 3,674
Buildings and structures	335 419		4,076
Machinery and equipment	284	323	3,455
Other	26	20	317
Total	¥947	¥ 2,364	\$11,522

Consumer products:			Thousands of U.S. Dollars
Consumer products.	2012.3	2011.3	2012.3
Goodwill	¥ —	¥137	\$ —
Total	¥ —	¥137	\$ <i>—</i>

Other:	Million	Millions of Yen		
Other.	2012.3	2011.3	2012.3	
Land	¥ 12	¥ —	\$ 146	
Buildings and structures	488	_	5,937	
Machinery and equipment	295	_	3,589	
Other	1	_	13	
Total	¥796	¥ —	\$ 9,685	

Idle assets:	Million	Thousands of U.S. Dollars	
ruie assets.	2012.3	2011.3	2012.3
Land	¥271	¥231	\$ 3,297
Machinery and equipment	_	26	_
Other	20	_	244
Total	¥291	¥257	\$ 3,541

# Notes to Consolidated Financial Statements

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries

The Group bases its grouping for assessing impairment losses on its business segments. However, certain assets, such as idle assets, are evaluated on an individual basis. The recoverable amounts in each business segment were measured mainly at their value in use. Discount rate of 7.5% was used for the computation of present value of future cash flows for the intangible assets in the Nutraceutical business. The use of a discount rate was omitted due to the negative cash flows for other assets. The recoverable amount of the impaired idle assets was measured at net realizable value as determined based mainly on real estate appraisals.

# 10. Short-term borrowings and long-term debt

Short-term borrowings at March 31, 2012 and 2011 represented loans, principally from banks. The weighted-average interest rates on these borrowings were 2.8% and 2.3% at March 31, 2012 and 2011, respectively.

Long-term debt at March 31, 2012 and 2011 consisted of the following:

	Million:	Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Secured loans from banks and financial institutions			
Due 2012 to 2015, with a weighted- average interest rate of 0.9% (2012) and due 2011 to 2015, with a weighted- average interest rate of 2.0% (2011)	¥ 96	¥ 1,469	\$ 1,168
Unsecured loans from banks and financial institutions			
Due 2012 to 2018, with a weighted- average interest rate of 0.9% (2012) and due 2011 to 2018, with a weighted- average interest rate of 0.9% (2011)	30,876	50,818	375,666
Lease liabilities			
Secured	225	426	2,738
Unsecured	8,536	10,007	103,857
Total	39,733	62,720	483,429
Less-portion due within one year			
Loans	5,024	23,523	61,127
Lease liabilities	2,974	3,371	36,184
Long-term debt, less current portion	¥31,735	¥35,826	\$386,118

Annual maturities of long-term debt at March 31, 2012 were as follows:

Years ending March 31		Thousands of U.S. Dollars
2013	¥ 7,998	\$ 97,311
2014	5,356	65,166
2015	22,500	273,756
2016	1,027	12,495
2017	1,518	18,469
2018 and thereafter	1,334	16,232
Total	¥39,733	\$483,429

The carrying amounts of assets pledged as collateral for long-term debt at March 31, 2012 were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Cash and cash equivalents	¥ 588	\$ 7,154
Receivables-trade accounts	756	9,198
Inventories	1,740	21,170
Property, plant, and equipment - net of accumulated depreciation	3,156	38,400
Total	¥6,240	\$ 75,922

## 11. Retirement benefits

Certain domestic consolidated subsidiaries have adopted retirement benefit plans consisting of lump-sum retirement payments, defined benefit pension

plans, and defined contribution pension plans. Certain foreign consolidated subsidiaries have adopted defined benefit pension plans or defined contribution pension plans, or a combination of the two.

Provisions have been made for employees' retirement benefits, based on an estimate of the projected retirement benefit obligation and the fair value of the pension fund assets.

The liability for employees' retirement benefits at March 31, 2012 and 2011 consisted of the following:

		Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Projected benefit obligation	¥196,331	¥ 194,750	\$ 2,388,746
Fair value of plan assets	(139,429)	(136,118)	(1,696,423)
Unrecognized prior service cost	2,878	3,513	35,016
Unrecognized actuarial loss	(15,071)	(17,749)	(183,368)
Unrecognized transitional obligation	_	(62)	_
Net liability	¥ 44,709	¥ 44,334	\$ 543,971

The components of net periodic retirement benefit costs for the years ended March 31, 2012 and 2011 are as follows:

	Million	Millions of Yen		
	2012.3	2011.3	2012.3	
Service cost	¥ 7,571	¥ 7,542	\$ 92,116	
Interest cost	4,210	4,203	51,223	
Expected return on plan assets	(3,678)	(3,552)	(44,750)	
Amortization of prior service cost	(596)	205	(7,251)	
Recognized actuarial loss	4,905	3,022	59,679	
Amortization of transitional obligation	62	273	754	
Net periodic benefit costs	12,474	11,693	151,771	
Additional benefit	474	309	5,767	
Contributions to defined contribution pension plan	2,140	2,126	26,037	
Total	¥15,088	¥14,128	\$183,575	

Assumptions used for the years ended March 31, 2012 and 2011 are set forth as follows:

	2012.3	2011.3
Discount rate	2.00%-7.00%	2.00%-9.00%
Expected rate of return on plan assets	2.50%-9.00%	2.50%-12.00%
Amortization period of prior service cost	5-23 years	5-23 years
Recognition period of actuarial gain/loss	5-15 years	5-15 years
Amortization period of transitional obligation	5-10 years	5-15 years

# 12. Equity

Japanese companies are subject to the Companies Act. The significant provisions in the Companies Act that affect financial and accounting matters are summarized below:

#### (a) Dividends

Under the Companies Act, companies can pay dividends at any time during the fiscal year in addition to the year-end dividend upon a resolution at the shareholders' meeting. More specifically, companies that meet the following criteria can provide in their articles of incorporation that the board of directors can declare dividends (except for dividends in kind) at their discretion. These criteria are: (1) the company must have a board of directors, (2) the company must have an independent auditor, (3) the company must have a board of corporate auditors, and (4) the term of service of the directors must be one year (rather than the normal term of two years). The Company meets all the above criteria.

The Companies Act provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than ¥3 million.

# (b) Increases/decreases and transfer of common stock, reserve, and surplus

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the total of aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reserved without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus, and retained earnings can be transferred among the accounts under certain conditions upon a resolution of the shareholders.

## (c) Treasury stock and treasury stock acquisition rights

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by a resolution of the board of directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders, which is determined by a specific formula. Under the Companies Act, stock acquisition rights are presented as a separate component of equity. The Companies Act also provides that companies can purchase both treasury stock acquisition rights and treasury stock. Such treasury stock acquisition rights are presented as a separate component of equity or deducted directly from stock acquisition rights.

#### Issuance of new shares through initial public offering

On December 15, 2010, the Company issued 38,678,800 new shares valued at  $\frac{1}{2}$ 77,490 million in an initial public offering of shares.

# 13. Stock options

The stock options outstanding as of March 31, 2012 are as follows:

Stock Option	Persons Granted	Number of Options Granted	Date of Grant	Exercise Price	Exercise Period
2010 Stock	11 Company directors	490,000	July 22,	¥ 1	From July 23, 2012
Option No. 1		shares	2010	(\$0)	to July 31, 2015
2010 Stock	Four Company corporate auditors	32,000	July 22,	¥ 2,100	From July 23, 2012
Option No. 2		shares	2010	(\$26)	to July 31, 2015
2010 Stock	Three wholly owned	150,000	July 22,	¥1	From July 23, 2012
Option No. 3	subsidiary directors	shares	2010	(\$0)	to July 31, 2015
2010 Stock Option No. 4	Five Company corporate officers, 31 subsidiary directors, four subsidiary corporate auditors, and 21 subsidiary corporate officers	620,000 shares	July 22, 2010	¥ 2,100 (\$26)	From July 23, 2012 to July 31, 2015

The stock option activity:

For the year ended March 31, 2012	2010 Stock Option No. 1	2010 Stock Option No. 2	2010 Stock Option No. 3	2010 Stock Option No. 4
Nonvested:				
March 31, 2011 – Outstanding		_	_	_
Granted	490,000 shares	32,000 shares	150,000 shares	620,000 shares
Canceled	_	_	_	_
Vested	_	_	_	
March 31, 2012 – Outstanding	490,000 shares	32,000 shares	150,000 shares	620,000 shares
Vested:				
March 31, 2011 – Outstanding	_	_	_	_
Vested	_	_	_	_
Exercised	_	_	_	_
Canceled	_	_	_	_
March 31, 2012 – Outstanding	_	_	_	
Exercise price	¥ 1 (\$0)	¥2,100 (\$26)	¥ 1 (\$0)	¥2,100 (\$26)
Average stock price at exercise	_	=	_	_
Fair value price at grant date	¥2,099 (\$26)	¥ 0 (\$0)	¥2,099 (\$26)	¥ 0 (\$0)

# The assumptions used to measure fair value of 2010 stock options

As the Company was a privately held company as of the grant date, the fair value of options at grant date is equal to the intrinsic value of the options at grant date.

# The assumptions used to measure the number of vested stock options

The Company uses only the actual cancellations due to the difficulty in determining reasonable estimates about the number of future cancellations.

# **Information regarding intrinsic value:**

- The total intrinsic value of the stock options for the years ended March 31, 2012 and 2011 was ¥1,796 million (\$21,852 thousand) and ¥1,315 million, respectively.
- 2) The total intrinsic value of the stock option rights on the exercise date: No information relevant for the fiscal year ended March 31, 2012 and 2011.

## 14. Income taxes

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in aggregate, resulted in a normal effective statutory tax rate of approximately 40.6% for each of the fiscal years ended March 31, 2012 and 2011.

Foreign consolidated subsidiaries are subject to income taxes in the countries in which they operate.

The tax effects of significant temporary differences and tax loss carryforwards, which resulted in deferred tax assets and liabilities, at March 31, 2012 and 2011 were as follows:

	Millions	Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Deferred tax assets:			
Liability for employees' retirement benefits	¥15,147	¥16,551	\$184,292
Unrealized intercompany profits from inventories	15,180	11,013	184,694
Accrued expenses	10,385	9,856	126,354
Accrued enterprise tax	3,132	1,276	38,107
Tax loss carryforwards	14,732	12,583	179,243
Research and development expenses	6,224	7,051	75,727
Loss on devaluation of investment securities	6,013	6,314	73,160
Loss on impairment of long-lived assets	2,446	2,373	29,760
Long-term unearned revenue	11,801	12,138	143,582
Other	9,787	8,164	119,078
Less valuation allowance	(28,231)	(24,952)	(343,485)
Total deferred tax assets	¥66,616	¥62,367	\$810,512
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	¥642	¥1,033	\$7,811
Unrealized gain on full revaluation resulting from inclusion of consolidated subsidiaries	6,128	6,389	74,559
Revaluation of brands	3,432	4,857	41,757
Other	4,834	4,193	58,815
Total deferred tax liabilities	¥15,036	¥16,472	\$182,942
Net deferred tax assets	¥51,580	¥ 45,895	\$627,570

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated financial statements of income for the years ended March 31, 2012 and 2011 was as follows:

	2012.3	2011.3
Normal effective statutory tax rate	40.6%	40.6%
Tax credit for research and development expenses	(12.1)	(9.8)
Reduction of ending deferred tax balance due to change in statutory tax rate $% \left( 1\right) =\left( 1\right) \left( 1$	2.4	_
Expenses not deductible for income tax purposes	2.1	2.4
Valuation allowance	3.9	1.0
Difference in statutory tax rate of subsidiaries	(0.1)	(0.8)
Equity in earnings of affiliated companies	(0.0)	(0.7)
Gain on change in equity interest	(0.1)	(1.8)
Other – net	(1.9)	0.8
Actual effective tax rate	34.8%	31.7%

On December 2, 2011, the "Act to Partially Revise the Income Tax Act and Others in Order to Construct a Tax System Corresponding to Changes in the Structure of Economic System" (Act No. 114 of 2011) and "Special Measures Act to Secure the Financial Resources Required to Implement Policy on Restoration after the Great East Japan Earthquake" (Act No. 117 of 2011) were promulgated. Under these acts, effective from the fiscal year beginning on or after April 1, 2012, the corporate income tax rate will be changed.

As a result, the effective statutory tax rates to calculate deferred tax assets and liabilities will be changed from 40.6% to 38.0% for temporary differences that are expected to be recovered or settled in the three consecutive fiscal years beginning on or after April 1, 2012, and from 40.6% to 35.6% for temporary differences that are expected to be recovered or settled in the fiscal years beginning on or after April 1, 2015.

Due to these revisions, deferred tax assets (net amount after deducting deferred tax liabilities) decreased by ¥3,322 million (\$40,419 thousand), unrealized gain on available-for-sale securities (plus in net assets) increased by ¥98 million (\$1,192 thousand), and income taxes-deferred (expense) increased by ¥3,420 million (\$41,611 thousand).

At March 31, 2012, certain consolidated subsidiaries had tax loss carryforwards aggregating ¥47,662 million (\$579,900 thousand), which are available to be offset against taxable income of such subsidiaries in future years. These tax loss carryforwards, if not utilized, will expire as follows:

Years Ending March 31	Millions of Yen	Thousands of U.S. Dollars
2013	¥ 1,546	\$ 18,810
2014	5,406	65,774
2015	3,085	37,535
2016	7,536	91,690
2017 and thereafter	30,089	366,091
Total	¥47,662	\$579,900

# 15. Up-front licensing payments received

Net sales recognized as revenue from the up-front licensing payments received were  $\pm 14,872$  million ( $\pm 180,947$  thousand) and  $\pm 7,323$  million for the years ended March 31, 2012 and 2011, respectively.

# 16. Selling, general, and administrative expenses

	Million	Thousands of U.S. Dollars	
	2012.3	2011.3	2012.3
Sales promotion expenses	¥174,380	¥179,555	\$2,121,669
Personnel expenses	99,842	97,870	1,214,771
Depreciation	14,707	14,063	178,939
Amortization of goodwill	4,667	4,614	56,783
Research and development expenses	159,230	164,671	1,937,340
Other	163,823	161,499	1,993,223
Selling, general, and administrative expenses	¥616,649	¥622,272	\$7,502,725

## 17. Disaster-related loss

Disaster-related loss for the year ended March 31, 2012 relates to the Great East Japan Earthquake of 2011 and primarily includes disaster relief money, costs for restoring buildings damaged in the disaster, and other costs. Disaster-related loss for the year ended March 31, 2011 also relates to the Great East Japan Earthquake of 2011 and primarily includes costs of exchanging damaged goods for customers in the disaster-stricken areas, monetary donations, and relief supplies.

# 18. Provision for loss on business liquidation

Provision for loss on business liquidation is the result of the consolidation and reduction of the specialty chemicals businesses.

#### 19. Leases

The Group leases certain assets, mainly machinery and equipment.

The future minimum lease payments under noncancelable operating leases at March 31, 2012 were as follows:

2012.3		Thousands of U.S. Dollars
Due within one year	¥ 2,235	\$ 27,193
Due after one year	8,326	101,302
Total	¥10,561	\$128,495

# 20. Related-party transactions

There were no material related-party transactions for the years ended March 31, 2012 and 2011.

# 21. Financial instruments and related disclosures

#### (1) Group policy for financial instruments

The Group limits its investments to low-risk financial assets and uses borrowings from financial institutions, mainly banks, for its financing needs.

Derivatives are used, not for speculative purposes, but to manage exposure to financial risks as described in (2) below.

# (2) Nature and extent of risks arising from financial instruments

Receivables, such as trade notes and trade accounts, are exposed to customer credit risk. Receivables in foreign currencies are also exposed to the market risk of fluctuation in foreign currency exchange rates. Marketable and investment securities, mainly held-to-maturity debt securities and available-for-sale equity securities, are exposed to the risk of market price fluctuations and credit risk.

Payment terms of payables, such as trade notes and trade accounts, are less than one year. Payables in foreign currencies are exposed to the market risk of fluctuation in foreign currency exchange rates. Part of the bank loans are exposed to market risks from changes in variable interest rates. Part of the bank loans in foreign currencies are also exposed to the market risk of fluctuation in foreign currency exchange rates.

Derivatives mainly include forward foreign currency contracts, which are used to manage exposure to market risks from changes in foreign currency exchange rates of receivables and payables, and interest rate swaps, which are used to manage exposure to changes in interest rates of bank loans. Please see Note 22 for more details about derivatives.

# (3) Risk management for financial instruments

# **Credit Risk Management**

Credit risk is the risk of economic loss arising from a counterparty's failure to repay or service debt according to the contractual terms. The Group manages its credit risk from receivables on the basis of internal guidelines, which include monitoring of payment term and balances of major customers to identify the default risk of customers in early stage. With respect to held-to-maturity investments, the Group manages its exposure to credit risk by limiting its funding to high credit rating bonds in accordance with its internal guidelines. Please see Note 22 for details about derivatives.

# Market risk management (foreign exchange risk and interest rate risk)

Foreign currency trade receivables and payables are exposed to market risk resulting from fluctuations in foreign currency exchange rates. Such foreign exchange risk is hedged principally by forward foreign currency contracts.

Marketable and investment securities are managed by monitoring market values and the financial position of issuers on a regular basis. Interest rate swaps are used to manage exposure to market risks from changes in interest rates of loan payables and bond payables. Please see Note 22 for details about derivatives.

## Liquidity risk management

Liquidity risk comprises the risk that the Group cannot meet its contractual obligation in full on the maturity date. The Group manages its liquidity risk by maintaining an adequate volume of liquid assets, along with adequate financial planning by the corporate treasury department.

## (4) Fair values of financial instruments

Fair values of financial instruments are based on the quoted prices in active markets. If a quoted price is not available, a theoretical value is calculated using a valuation technique that is based on internal assumptions. A change in such assumptions may result in a different value. Also, please see Note 22 for the details of fair value for derivatives.

(a) Fair value of financial instruments whose fair value can be reliably determined

	Millions of Yen				
March 31, 2012	Carrying amount				
Cash and cash equivalents	¥384,194	¥ 384,194	¥ —		
Time deposits	142,570	142,570	_		
Receivables	279,853	279,853	_		
Marketable and investment securities	133,339	133,793	454		
Investments in unconsolidated subsidiaries and affiliated companies	27,623	70,827	43,204		
Total	¥967,579	¥ 1,011,237	¥43,658		
Short-term borrowings	¥ 34,668	¥ 34,668	¥ —		
Payables	145,322	145,322	_		
Income tax payable	33,823	33,823	_		
Long-term debt (excluding lease liabilities)	30,972	30,994	22		
Total	¥244,785	¥ 244,807	¥ 22		

	Millions of Yen					
March 31, 2011	Carrying amount	Fair value	Unrealized gain			
Cash and cash equivalents	¥387,326	¥387,326	¥ —			
Time deposits	91,195	91,195				
Receivables	254,695	254,695	_			
Marketable and investment securities	123,123	123,613	490			
Investments in unconsolidated subsidiaries and affiliated companies	26,893	77,173	50,280			
Total	¥883,232	¥934,002	¥50,770			
Short-term borrowings Payables	¥ 29,683 133.733	¥ 29,683 133.733	¥ —			
Income tax payable	13,733	13,755	_			
Long-term debt (excluding lease liabilities)	52,287	52,293	6			
Total	¥229,004	¥229,010	¥ 6			

	Thousands of U.S. Dollars					
March 31, 2012	Carrying amount	Fair value	Unrealized gain			
Cash and cash equivalents	\$ 4,674,462	\$ 4,674,462	\$ —			
Time deposits	1,734,639	1,734,639	_			
Receivables	3,404,952	3,404,952	_			
Marketable and investment securities	1,622,326	1,627,850	5,524			
Investments in unconsolidated subsidiaries and affiliated companies	336,087	861,747	525,660			
Total	\$ 11,772,466	\$12,303,650	\$531,184			
Short-term borrowings Payables Income tax payable Long-term debt (excluding lease liabilities)	\$ 421,803 1,768,123 411,522 376,834	\$ 421,803 1,768,123 411,522 377,102	\$ — — — — 268			
Total	\$ 2,978,282	\$ 2,978,550	\$ 268			

#### Cash and cash equivalents, time deposits, and receivables

The carrying values of cash and cash equivalents, time deposits, and receivables approximate fair value because of their short maturities.

# Marketable and investment securities and investments in unconsolidated subsidiaries and affiliated companies

The fair values of marketable and investment securities are measured at the quoted market price of the stock exchange for the equity instruments and at the quoted price obtained from the financial institution for certain debt instruments. The information regarding the fair value for the marketable and investment securities by classification is included in Note 7.

### Payables, short-term borrowings, and income tax payable

The carrying values of payables, short-term borrowings, and income tax payable approximate fair value because of their short maturities.

# Notes to Consolidated Financial Statements

Otsuka Holdings Co., Ltd. and Consolidated Subsidiaries

#### Long-term debt (including current portion of long-term debt)

The fair value of long-term debt is determined by discounting the principal and interest payments at the refinancing rate.

#### **Derivatives**

The information of the fair value for derivatives is included in Note 22.

(b) Financial instruments whose fair values cannot be reliably determined

	Million:	Thousands of U.S. Dollars		
	Carrying amount			
	2012.3	2012.3		
Investments in unconsolidated subsidiaries and affiliated companies	¥153,358	¥150,333	\$1,865,896	
Investment securities	¥ 11,611	¥ 11,581	\$ 141,270	

(c) Maturity analysis for financial assets and securities with contractual maturities

	Millions of Yen				
March 31, 2012	Due in one year or less	Due after one year through five years	Due after five years through 10 years	Due after 10 years	
Cash and cash equivalents	¥384,194	¥ —	¥ —	¥ —	
Time deposits	142,570	_	_	_	
Receivables	279,954	284	5	_	
Marketable and investment securities:					
Held-to-maturity securities	36,600	51,000	2,000	1,000	
Total	¥843,318	¥51,284	¥2,005	¥1,000	

	Thousands of U.S. Dollars				
March 31, 2012	Due in one year or less	Due after one year through five years	Due after five years through 10 years	Due after 10 years	
Cash and cash equivalents	\$ 4,674,462	\$ —	\$ —	\$ —	
Time deposits	1,734,639	_	_	_	
Receivables	3,406,181	3,455	61	_	
Marketable and investment securities:					
Held-to-maturity securities	445,310	620,514	24,334	12,167	
Total	\$10,260,592	\$623,969	\$24,395	\$12,167	

Please see Note 10 for annual maturities of long-term debt and obligations under finance leases.

# 22. Derivatives

The Group enters into foreign currency forward contracts to hedge foreign exchange risk associated with certain assets and liabilities denominated in foreign currencies. The Group also enters into foreign currency option contracts (zero-cost options) to obtain U.S. dollars for the payment of foreign currency payables. The Group also enters into interest rate swap contracts to manage its interest rate exposures on certain debts.

All derivative transactions are entered into hedge interest and foreign currency exposures incorporated within the Group's business. Accordingly, market risk in these derivatives is basically offset by opposite movements in the value of hedged assets or liabilities.

Because the counterparties to these derivatives are limited to major international financial institutions, the Group does not anticipate any losses arising from credit risk.

Derivatives transactions entered into by the Group have been made in accordance with internal policies, which regulate the authorization and credit limit amount.

Derivative transactions to which hedge accounting is not applied at March 31,2012 and 2011

	Millions of Yen				
At March 31, 2012		Contract amount due after one year	Fair value	Unrealized loss	
Foreign currency forward contracts:					
Buying U.S. \$	¥ 482	¥ —	¥ (2)	¥ (2)	
Buying Euro	1,945	_	(3)	(3)	
Buying JP¥	13	_	_	_	
Foreign exchange option:					
U.S. \$	2,663	_	(531)	(531)	
Total	¥ 5,103	¥	¥(536)	¥ (536)	

	Millions of Yen			
At March 31, 2011	Contract amount	Contract amount due after one year		Unrealized loss
Foreign currency forward contracts:				
Buying U.S. \$	¥ 268	¥ —	¥ —	¥ —
Buying Euro	213	_	(3)	(3)
Buying JP¥	2	_	_	_
Selling U.S. \$	324	_	(5)	(5)
Foreign exchange option:				
U.S. \$	5,532	2,663	(1,072)	(1,072)
Total	¥ 6,339	¥ 2,663	¥(1,080)	¥(1,080)
Interest rate swaps				
(floating rate receipt, floating rate payment)	¥10,423	¥ —	¥ (327)	¥ (327)
Total	¥10,423	¥ —	¥ (327)	¥ (327)

	Thousands of U.S. Dollars				
At March 31, 2012	Contract amount	Contract amount due after one year		Unrealized loss	
Foreign currency forward contracts:					
Buying U.S. \$	\$ 5,864	\$ —	\$ (24)	\$ (24)	
Buying Euro	23,665	_	(37)	(37)	
Buying JP¥	158	_	_	_	
Foreign exchange option:					
U.S. \$	32,401	_	(6,461)	(6,461)	
Total	\$62,088	\$ <i>—</i>	\$ (6,522)	\$ (6,522)	

Derivative transactions to which hedge accounting is applied at March 31, 2012 and 2011

	Millions of Yen				
At March 31, 2012	Hedged item	Contract amount	Contract amount due after one year	Fair value	
Foreign currency forward contracts:					
Buying U.S. \$	Forecasted transactions	¥ 218	¥ —	¥ 15	
Interest rate swaps:					
(fixed rate payment, floating rate receipt)	Long-term debt	¥1,800	¥800	¥ (14)	

		Millions of Yen					
At March 31, 2011	Hedged item	Contract amount due after one year		Fair value			
Foreign currency forward contracts:							
Buying U.S. \$	Forecasted transactions	¥ 423	¥ —	¥ (6)			
Interest rate swaps:							
(fixed rate payment, floating rate receipt)	Long-term debt	¥1,910	¥1,000	¥ (18)			

	Thousands of U.S. Dollars				
At March 31, 2012	Hedged item	Contract amount	Contract amount due after one year	Fair value	
Foreign currency forward contracts:					
Buying U.S. \$	Forecasted transactions	\$ 2,652	\$ <b>—</b>	\$ 183	
Interest rate swaps:					
(fixed rate payment, floating rate receipt)	Long-term debt	\$21,900	\$9,734	\$(170)	

The fair value of derivative transactions is measured at the quoted price obtained from the financial institution.

The contract or notional amounts of derivatives, which are shown in the above table, do not represent the amounts exchanged by the parties and do not measure the Group's exposure to credit or market risk.

# 23. Contingent liabilities

At March 31, 2012, the Group had the following contingent liabilities:

		Thousands of U.S. Dollars
Trade notes discounted	¥ 278	\$ 3,382
Guarantees and similar items of bank loans	¥ 4,868	\$ 59,229

On April 4, 2009, Otsuka Pharmaceutical Co., Ltd., a consolidated subsidiary of the Company, signed an agreement with Bristol-Myers Squibb Company (BMS) to extend the contract period for the U.S. portion of the development and commercialization collaboration agreement for ABILIFY from November 2012 to April 2015, and to increase the profit share of ABILIFY U.S. net sales that Otsuka Pharmaceutical Co., Ltd., records effectively in January 2010. Under the terms of the agreement, Otsuka Pharmaceutical Co., Ltd., received \$400 million in April 2009, which was recorded as unearned revenue and long-term unearned revenue, and is amortized as revenue over the period beginning on January 1, 2010, until the end of the contract in April 2015. The balance of the amount of the up-front payment received, reduced by the amortization, is recorded as unearned revenue and long-term unearned revenue at each fiscal year end. In the current fiscal year, ¥7,321 million were recognized as net sales.

In addition to the above, Otsuka Pharmaceutical Co., Ltd., and BMS entered into a contract regarding the anticancer agents SPRYCEL and IXEMPRA as described below, and revenues associated with this contract have been recognized effective from January 1, 2010.

- a. Otsuka Pharmaceutical Co., Ltd. codevelops and copromotes SPRYCEL with BMS in the U.S., Japan and major countries in Europe, and incurs certain expenses in the U.S., Europe and Japan.
- b. From 2010 to 2020, Otsuka Pharmaceutical Co., Ltd. receives a profit share based on the total sales amount of SPRYCEL and IXEMPRA.

With regard to the aforementioned contracts, a provision went into effect on January 1, 2010, stipulating that if during the above contract period generic products of ABILIFY were launched in the U.S. and BMS requests cancellation of the contract, Otsuka Pharmaceutical Co., Ltd. is obligated to pay compensation including the above up-front payment as agreed upon under the agreement. The amount of the compensation minus the unearned revenue balance represents the contingent liability at each fiscal year end. As of March 31, 2012, the contingent liability balance was ¥63,231 million. BMS also retains the right to cancel the contracts for SPRYCEL and IXEMPRA in the event generic products of ABILIFY are launched in the U.S. prior to February 22, 2014.

In the U.S., Otsuka Pharmaceutical Co., Ltd. filed patent infringement actions against a number of generic drug companies, which had sought FDA approval to commercialize generic versions of ABILIFY.

The U.S. Court issued the judgment of first instance dated November 15, 2010 and the judgment of second instance dated May 7, 2012 in favor of Otsuka Pharmaceutical Co., Ltd. However, one of these generic drug companies has filed notices of appeal to the U.S. Court of Appeals for the Federal Circuit challenging the May 7, 2012 judgment.

# 24. Comprehensive income

The components of other comprehensive income for the year ended March 31, 2012 were as follows:

2012.3	Millions of Yen	Thousands of U.S. Dollars
Unrealized gain on available-for-sale securities:		
Gains arising during the year	¥ —	\$ —
Reclassification adjustments to profit or loss	100	1,217
Amount before income tax effect	100	1,217
Income tax effect	200	2,433
Total	¥ 300	\$ 3,650
Deferred (loss) gain on derivatives under hedge accounting:		
Gains arising during the year	¥ (4)	\$ (48)
Reclassification adjustments to profit or loss	25	304
Amount before income tax effect	21	256
Income tax effect	(6)	(73)
Total	¥ 15	\$ 183
Foreign currency translation adjustments:		
Adjustments arising during the year	¥(4,999)	\$(60,822)
Reclassification adjustments to profit or loss	108	1,313
Amount before income tax effect	(4,891)	(59,509)
Income tax effect	_	_
Total	¥(4,891)	\$(59,509)
Share of other comprehensive income in associates:		
Gains arising during the year	¥(2,977)	\$(36,221)
Reclassification	(47)	(572)
Total	¥(3,024)	\$(36,793)
Total other comprehensive income	¥(7,600)	\$(92,469)

The corresponding information for the year ended March 31, 2011 was not required under the accounting standard for presentation of comprehensive income as an exemption for the first year of adopting that standard and not disclosed herein.

# 25. Cash flow information

# (1) Assets and liabilities of business transfers resulting in proceeds for the fiscal years ended March 31, 2012 and 2011

The following are the details of assets and liabilities of the Sanutri business at the time of transfer by Nutrition & Santé Iberia SL and price and proceeds for the transfer:

2012.3	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥ 217	\$ 2,640
Noncurrent assets	1,849	22,497
Cost of transferred business	2,066	25,137
Loss on transfer of business	(684)	(8,322)
Price for transferred business	1,382	16,815
Proceeds from transfer of business	¥ 1,382	\$16,815

The following are the details of assets and liabilities of the AgriTechno business at the time of transfer by Otsuka Chemical Co., Ltd. and price and proceeds for the transfer:

2011.3	Millions of Yen
Current assets	¥ 5,095
Noncurrent assets	1,734
Current liabilities	(1,592)
Long-term liabilities	(735)
Other comprehensive income	(1)
Cost of transferred business	4,501
Loss on transfer of business	(1,901)
Price for transferred business	2,600
Cash and cash equivalent, transferred business	(500)
Proceeds from transfer of business	¥ 2,100

# (2) Assets and liabilities of business transferred resulting in payments for the fiscal year ended March 31, 2012.

The following are the details of assets and liabilities and price and payments for the acquisition of Natursoy business by Nutrinat AG:

	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥ —	\$ —
Noncurrent assets	(1,278)	(15,549)
Current liabilities	_	_
Long-term liabilities	_	_
Cost of transferred business	(1,278)	(15,549)
Price for transferred business	(1,278)	(15,549)
Payments for transfer of business	¥(1,278)	\$(15,549)

#### (3) Nonmonetary transactions.

There were no nonmonetary transactions with a materiality for disclosure for the years ended March 31, 2012 and 2011.

# 26. Net income per share

The following is a reconciliation of the differences between basic and diluted net income per share (EPS) for the years ended March 31, 2012 and 2011:

	Millions of Yen	Thousands of shares	Yen	U.S.Dollars
For the year ended March 31, 2012	Net income	Weighted- average shares	EPS	
Basic EPS				
Net income available to common shareholders	¥92,156	557,832	¥165.20	\$ 2.01
Effect of dilutive securities				
Warrants	(173)	_		
Stock options	_	552		
Diluted EPS				
Net income for computation	¥91,983	558,384	¥164.73	\$ 2.00

	Millions of Yen	Thousands of shares	Yen EPS	
For the year ended March 31, 2011	Net income	Weighted- average shares		
Basic EPS				
Net income available to common shareholders	¥82,357	500,599	¥164.52	
Effect of dilutive securities				
Warrants	(23)	_		
Stock options	_	207		
Diluted EPS				
Net income for computation	¥82,334	500,806	¥164.40	

# Change in the method of translating revenue and expense accounts of foreign subsidiaries and affiliated companies

Previously, revenue and expense accounts of foreign subsidiaries and affiliated companies were translated into Japanese yen at the current exchange rate prevailing as of the balance sheet date of such foreign subsidiaries and affiliated companies. From the current fiscal year, the Group changed to the average exchange rate. The Group changed its method of translation to more accurately reflect the performances of foreign subsidiaries and affiliated companies in the consolidated financial statements by mitigating the effects of temporary fluctuations in exchange rates and taking into consideration importance of foreign subsidiaries and affiliated companies.

The prior-year consolidated financial statements for the full year have been adjusted retrospectively to apply the change in accounting policy.

The effects of the change in translation method were to increase the prior year's basic and diluted earnings per share by ¥2.74 and ¥2.66, respectively.

# Application of accounting standards relating to earnings per share

Effective from the current fiscal year, the Company applied "Accounting Standard for Earnings Per Share" (ASBJ Statement No. 2 revised on June 30, 2010), "Guidance on Accounting Standard for Earnings Per Share" (ASBJ Guidance No. 4 revised on June 30, 2010), and "Practical Solution on Accounting for Earnings Per Share" (ASBJ PITF No. 9 revised on June 30, 2010).

The method of computing diluted net income per share has been changed concerning the treatment of stock options that become exercisable after a certain period of service. Specifically, of such stock options' fair value, the portion attributable to service yet to be provided to the Company is now included in the amount to be paid upon exercise of the stock options.

As a result, the effect of the change was to increase the prior year's diluted earnings per share by ¥0.14.

# 27. Subsequent events

## **Appropriation of retained earnings**

The following appropriation of retained earnings at March 31, 2012 was approved at a meeting of the Company's board of directors held on May 11, 2012:

	Millions of Yen	Thousands of U.S. Dollars
Year-end cash dividends, ¥25.0(\$0.30) per share	¥13,946	\$169,680

#### **Purchase of treasury stock**

On June 13, 2012, the board of directors resolved to purchase up to 9 million shares of its common stock at cost up to \$20,000 million in accordance with the Companies Act.

As a result, the Company repurchased 7,228,500 shares at a cost of ¥17,471 million on June 15, 2012.

# 28. Segment information

## For the years ended March 31, 2012 and 2011

Under ASBJ Statement No. 17, "Accounting Standard for the Segment Information Disclosures," and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Segment Information," an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and such information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

#### 1. Overview

The Group's reporting segments are the constituent units of the Group for which separate financial information is available and which are subject to periodic reviews by the board of directors, in order to make decisions on allocation of business resources and to evaluate the business performances of the respective segments.

The Group's core business is in healthcare and the Group categorizes the "Pharmaceuticals," "Nutraceuticals," "Consumer products," and "Other" businesses as the four reporting segments.

The Group defines the reporting segments as follows:

- Pharmaceuticals, which is composed of research and development, production and sales of prescription drugs and clinical nutrition.
- Nutraceuticals, which is composed of production and sales of functional foods, over-the-counter drugs and supplements.
- •Consumer products, which is composed of mineral water, beverages, and food products.
- Other, which encompasses other operations, composed of logistics, warehousing, chemical products, and electronics.

# **2.** Calculation methods for sales, profit (loss), assets, and other items (Note regarding changes to reporting segment)

In conjunction with the changes, as in Note 3, "Changes in Accounting Policies," and Note 4, "Changes in Method of Presentation," the Group changed the calculation method of sales, segment profit (loss), assets, and other items by reporting segment. These changes have been applied retrospectively.

(Change in the method of translating revenue and expense accounts of foreign subsidiaries and affiliated companies)

Previously, revenue and expense accounts of foreign subsidiaries and affiliated companies were translated into Japanese yen at the current exchange rate prevailing as of the balance sheet date of such foreign subsidiaries and affiliated companies. From the current fiscal year, the Group changed to the average exchange rate. The Group changed its method of translation to more accurately reflect the performances

of foreign subsidiaries and affiliated companies in the consolidated financial statements by mitigating the effects of temporary fluctuations in exchange rates and taking into consideration importance of foreign subsidiaries and affiliated companies.

The prior-year consolidated financial statements for the full year have been adjusted retrospectively to apply the change in accounting policy.

(Change in the method of presentation for up-front licensing payments received)
Previously, up-front licensing payments received were recorded as "revenues related to extension of co-promotion agreement" and "other" under other income. However, as such, income is directly attributable to the core business activities in the pharmaceutical business and, as such, transactions are likely to grow in importance, the Group has changed its method of presentation to include such income as net sales from the current fiscal year.

"Information about sales, profit (loss), assets, and other items" for the year ended March 31, 2011 has been reclassified to reflect the change in the method of presentation.

"Information about sales, profit (loss), assets, and other items" for the year ended March 31, 2011 before retrospective adjustment of the above two changes is presented in "11. Information about sales, profit (loss), assets, and other items before retrospective application and adjustments for the fiscal year ended March 31, 2011."

#### 3. Information about sales, profit (loss), assets, and other items

	Millions of Yen								
2012.3	Reportable segment								Constituted
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Total	Reconciliations	Consolidated		
Sales									
Sales to external customers	¥782,248	¥251,282	¥ 47,990	¥ 73,054	¥ 1,154,574	¥ —	¥ 1,154,574		
Intersegment sales and transfers	_	3,543	1,217	35,549	40,309	(40,309)	_		
Total	782,248	254,825	49,207	108,603	1,194,883	(40,309)	1,154,574		
Segment profit (loss)	168,481	22,144	(2,309)	1,943	190,259	(41,597)	148,662		
Segment assets	501,030	184,462	130,708	121,391	937,591	729,176	1,666,767		
Other:									
Depreciation	19,939	11,276	1,954	4,946	38,115	5,280	43,395		
Amortization of goodwill	2,749	1,703	74	141	4,667	_	4,667		
Investment in equity-method affiliated companies	17,543	8,637	102,762	10,715	139,657	_	139,657		
Increase in property, plant, and equipment and intangible assets	20,811	11,502	1,970	4,556	38,839	4,463	43,302		

	Millions of Yen							
2011.3			Reconciliations	Consolidated				
	Pharmaceuticals	Nutraceuticals	Consumer products	Other		Reconcinations	Consolidated	
Sales								
Sales to external customers	¥751,086	¥256,436	¥ 47,135	¥ 72,932	¥ 1,127,589	¥ —	¥ 1,127,589	
Intersegment sales and transfers	_	2,277	779	33,941	36,997	(36,997)	_	
Total	751,086	258,713	47,914	106,873	1,164,586	(36,997)	1,127,589	
Segment profit (loss)	142,783	18,421	(2,177)	4,372	163,399	(37,107)	126,292	
Segment assets	459,308	189,008	134,959	119,068	902,343	687,374	1,589,717	
Other:								
Depreciation	19,453	13,101	806	4,980	38,340	5,143	43,483	
Amortization of goodwill	2,629	1,703	132	150	4,614	_	4,614	
Investment in equity-method affiliated companies	14,346	8,961	108,334	10,337	141,978	_	141,978	
Increase in property, plant, and equipment and intangible assets	24,484	11,884	828	2,905	40,101	4,692	44,793	

	Thousands of U.S. Dollars							
2012.3			Reconciliations					
	Pharmaceuticals	Nutraceuticals	Consumer products	Other			Consolidated	
Sales								
Sales to external customers	\$ 9,517,557	\$ 3,057,330	\$ 583,891	\$ 888,843	\$ 14,047,621	s —	\$ 14,047,621	
Intersegment sales and transfers	_	43,108	14,807	432,522	490,437	(490,437)	_	
Total	9,517,557	3,100,438	598,698	1,321,365	14,538,058	(490,437)	14,047,621	
Segment profit (loss)	2,049,897	269,424	(28,093)	23,640	2,314,868	(506,108)	1,808,760	
Segment assets	6,095,997	2,244,336	1,590,315	1,476,956	11,407,604	8,871,834	20,279,438	
Other:								
Depreciation	242,597	137,194	23,774	60,178	463,743	64,241	527,984	
Amortization of goodwill	33,447	20,720	900	1,716	56,783	_	56,783	
Investment in equity-method affiliated companies	213,444	105,086	1,250,298	130,369	1,699,197	_	1,699,197	
Increase in property, plant, and equipment and intangible assets	253,206	139,944	23,969	55,432	472,551	54,301	526,852	

#### Notes:

- 1) Adjustments to segment profit of ¥41,597 million (\$506,108 thousand) include intersegment eliminations of ¥594 million (\$7,227 thousand) and unallocated corporate expenses of ¥42,191 million (\$513,335 thousand) for the year ended March 31, 2012. Adjustments to segment profit of ¥37,107 million include intersegment eliminations of ¥1,737 million and unallocated corporate expenses of ¥38,844 million for the year ended March 31, 2011. Corporate expenses include costs associated with headquarter functions.
- 2) Adjustments to segment assets of ¥729,176 million (\$8,871,834 thousand) include intersegment eliminations of ¥6,304 million (\$76,700 thousand) and corporate assets of ¥735,480 million (\$8,948,534 thousand) for the year ended March 31, 2012. Adjustments to segment assets of ¥687,374 million include intersegment eliminations of ¥6,718 million and corporate assets of ¥694,092 million for the year ended March 31, 2011. Corporate assets include assets associated with headquarter and research institutes.
- 3) Adjustments to depreciation consist of depreciation of tangible fixed assets, intangible fixed assets, and prepaid expenses-long-term for common properties of the Company and some consolidated subsidiaries' headquarters.
- 4) Adjustments to increase in property, plant, and equipment and intangible assets consist of capital expenditure for common properties of the Company and some consolidated subsidiaries' headquarters and research institutes.
- 5) Segment profit (loss) is adjusted to the operating income in the consolidated statements of income.

# 4. Information about products and services

2042.2		Millions of Yen				
2012.3	ABILIFY	Other	Total			
Sales to external customers	¥411,565	¥743,009	¥1,154,574			
2011.2						
2011.3	ABILIFY	Other	Total			
Sales to external customers	¥392,591	¥734,998	¥1,127,589			
2042.2			f U.S. Dollars			
2012.3	ABILIFY	Other	Total			
Sales to external customers	\$5,007,482	\$9,040,139	\$14,047,621			

## 5. Information about geographical areas

# (1) Sales

Millions of Terr									
2012.3									
Japan North America Other Total									
¥574,869	¥413,509	¥166,196	¥1,154,574						
	Milli								
	. 2	011.3							
Japan	North America	Other	Total						
¥575,053	¥402,727	¥149,809	¥1,127,589						
	Thousand	s of U.S. Dollars							
	_								

Japan	North America	Other	Total
\$6,994,391	\$5,031,135	\$2,022,095	\$14,047,621

Note: Sales are classified in countries or regions based on location of customers.

# (2) Property, plant, and equipment

Millions of Yen										
	2012.3									
Japan	Japan Other Total									
¥206,443	¥49,072	¥255,515								
Millions of Yen										
	2011.3									
Japan	Other	Total								
¥210,151	¥46,682	¥256,833								
	Thousands of U.S. Dollars									
	2012.3									
Japan	Total									
\$2,511,777	\$597,056	\$3,108,833								

#### 6. Information about major customers

Cardinal Health Inc.

McKesson Corporation

	Millions of Yen			
2012.3		Segment		
Cardinal Health Inc.	¥122,489	Pharmaceuticals		
McKesson Corporation	¥117,590	Pharmaceuticals		
2011.3	Million	ons of Yen		
2011.5	¥117,590	Segment		
Cardinal Health Inc.	¥115,801	Pharmaceuticals		
McKesson Corporation	¥111,706	Pharmaceuticals		
	Thousands	of U.S. Dollars		
2012.3	modanda			

¥1,490,315

¥1,430,709

Pharmaceuticals

Pharmaceuticals

## 7. Information about impairment losses on fixed assets

2012.3	Millions of Yen					
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Impairment losses	¥ 651	¥ 947	_	¥ 796	¥ 291	¥ 2,685

	Millions of Yen						
2011.3	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Impairment losses	_	¥2,364	¥ 137	¥ —	¥ 257	¥2,758	

2012.3	Thousands of U.S. Dollars						
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Impairment losses	\$ 7,920	\$11,522	_	\$ 9,685	\$ 3,541	\$32,668	

# 8. Information about amortization of goodwill and goodwill balance

	Millions of Yen						
2012.3	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Amortization of goodwill	¥2,749	¥ 1,703	¥ 74	¥ 141	_	¥ 4,667	
Goodwill at March 31, 2012	¥ 5,166	¥28,869	¥600	¥2,190	_	¥36,825	

2011.3	Millions of Yen						
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Amortization of goodwill	¥2,629	¥ 1,703	¥132	¥ 150	_	¥ 4,614	
Goodwill at March 31, 2011	¥7,915	¥30,572	¥641	¥2,317	_	¥41,445	

2012.3	Thousands of U.S. Dollars						
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Amortization of goodwill	\$33,447	\$ 20,720	\$ 900	\$ 1,716	_	\$ 56,783	
Goodwill at March 31, 2012	\$62,854	\$351,247	\$7,300	\$26,646	_	\$448,047	

# 9. Information about amortization of negative goodwill arising before April 1, 2010

2012.3	Millions of Yen						
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Amortization of negative goodwill	¥ 2,208	_	_	¥ 257	_	¥ 2,465	
Negative goodwill at March 31, 2012	¥23,871	_	_	¥2,598	_	¥26,469	

2011.3	Millions of Yen							
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total		
Amortization of negative goodwill	¥ 2,208	_	_	¥ 288	_	¥ 2,496		
Negative goodwill at March 31, 2011	¥26,079	_	_	¥2,854	_	¥28,933		

2012.3	Thousands of U.S. Dollars						
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total	
Amortization of negative goodwill	\$ 26,865	_	_	\$ 3,127	_	\$ 29,992	
Negative goodwill at March 31, 2012	\$290,437	_	_	\$31,609	_	\$322,046	

#### 10. Information about gain on negative goodwill

In the fiscal years ended March 31, 2012 and 2011, there was no gain on negative goodwill other than the amortization of pre-2011 amounts.

#### 11. Information about sales, profit (loss), assets, and other items before retrospective application and adjustments for the fiscal year ended March 31, 2011:

	Millions of Yen						
2011.3							
	Pharmaceuticals	Nutraceuticals	Consumer products	Other		Reconciliations	Consolidated
Sales							
Sales to external customers	¥721,402	¥249,489	¥46,752	¥72,570	¥1,090,213	¥ —	¥1,090,213
Intersegment sales and transfers	_	2,268	692	33,941	36,901	(36,901)	_
Total	721,402	251,757	47,444	106,511	1,127,114	(36,901)	1,090,213
Segment profit (loss)	134,433	17,861	(2,082)	4,351	154,563	(37,060)	117,503
Segment assets	459,231	189,008	134,959	119,068	902,266	687,374	1,589,640
Other:							
Depreciation	17,818	14,241	778	4,948	37,785	5,183	42,968
Amortization of goodwill	2,629	1,703	132	150	4,614	_	4,614
Investment in equity-method affiliated companies	14,346	8,961	108,335	10,336	141,978	_	141,978
Increase in property, plant, and equipment and intangible assets	24,263	11,514	804	2,889	39,470	4,691	44,161

#### Notes:

- 1) Adjustments to segment profit of ¥37,060 million include intersegment eliminations of ¥1,736 million and unallocated corporate expenses of ¥38,796 million for the year ended March 31, 2011. Corporate expenses include costs associated with headquarter functions.
- 2) Adjustments to segment assets of ¥687,374 million include intersegment eliminations of ¥6,717 million and corporate assets of ¥694,091 million for the year ended March 31, 2011. Corporate assets include assets associated with headquarter and research institutes.
- 3) Adjustments to depreciation consist of depreciation of tangible fixed assets, intangible fixed assets, and prepaid expenses-long-term for common properties of the Company and some consolidated subsidiaries' headquarters.
- 4) Adjustments to increase in property, plant, and equipment and intangible assets consist of capital expenditure for common properties of the Company and some consolidated subsidiaries' headquarters and research institutes.
- 5) Segment profit is adjusted to the operating income in the consolidated statements of income.



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#### INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of Otsuka Holdings Co., Ltd.:

We have audited the accompanying consolidated balance sheet of Otsuka Holdings Co., Ltd. and consolidated subsidiaries as of March 31, 2012, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in conformity with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in conformity with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Otsuka Holdings Co., Ltd. and consolidated subsidiaries as of March 31, 2012, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

#### Emphasis of Matter

As discussed in Note 3 to the consolidated financial statements, previously, revenue and expense accounts of foreign subsidiaries and affiliated companies were translated into Japanese yen at the current exchange rate as of the balance sheet date of such foreign subsidiaries and affiliated companies. From the current fiscal year, such accounts are translated at the average exchange rate for the year. Our opinion is not qualified in respect of this matter.

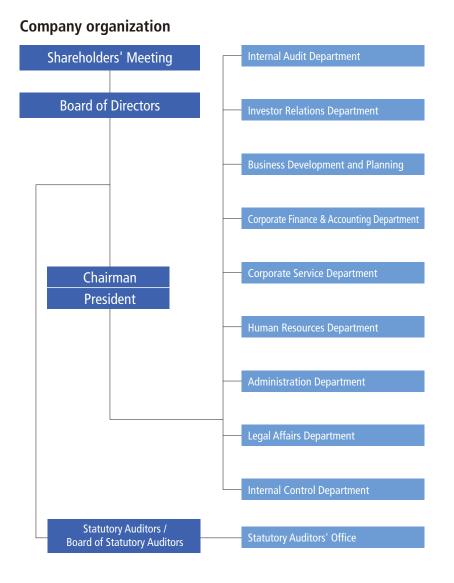
Member of Deloitte Touche Tohmatsu Limited As discussed in Note 4 to the consolidated financial statements, previously, up-front licensing payments received were recorded as "revenues related to extension of co-promotion agreement" and "other" included in other income. The Group has changed its method of presentation to include such income as net sales from the current fiscal year. Our opinion is not qualified in respect of this matter.

#### Convenience Translation

Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in conformity with the basis stated in Note 1. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

Deloitee Touche Tohmatsu LLC

June 22, 2012



## **Board of directors**

Chairman, Representative Director

Akihiko Otsuka

President and Representative Director, CEO

Tatsuo Higuchi

Senior Vice President

Ichiro Otsuka

Senior Managing Director, Finance

Atsumasa Makise

Managing Director, Administration

Yoshiro Matsuo

**Executive Directors** 

Yujiro Otsuka Yukio Kobayashi

**Standing Statutory Auditor** 

Masatoshi Taniguchi

**External Statutory Auditors** 

Yasuhisa Katsuta Norikazu Yahagi Hiroshi Sugawara

# Corporate profile (as of March 31, 2012)

Company name Otsuka Holdings Co., Ltd.

Established July 8, 2008
Capital ¥ 81.69 billion

Registered address 2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan

Tokyo headquarters Shinagawa Grand Central Tower, 2-16-4 Konan, Minato-ku, Tokyo 108-8241, Japan

Tel +81-3-6717-1410

Number of employees 65 (Consolidated: 24,595)

Business description Control, management and related activities with respect to the Company's subsidiaries and affiliates

active in the pharmaceutical industry, nutraceutical industry, consumer products and other areas.

Public notices http://www.otsuka.com/en/

As of March 31, 2012

Number of shares authorized 1,600,000,000

Number of shares issued 557,835,617

Number of shareholders 43,720

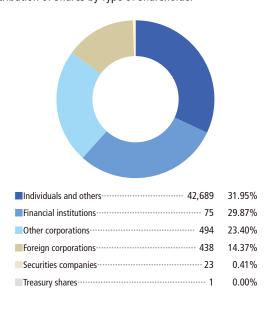
# **Principal shareholders**

Name	Number of shares held (thousands)	Percentage of voting rights (%)
The Nomura Trust and Banking Co., Ltd. (Otsuka Founders Shareholding Fund Trust Account)	65,029	11.65
Otsuka Estate Ltd.	40,629	7.28
Otsuka Group Employee Shareholding Fund	28,540	5.11
Japan Trustee Services Bank, Ltd. (Trust Account)	20,081	3.59
The Master Trust Bank of Japan, Ltd. (Trust Account)	17,217	3.08
Otsuka Asset Co., Ltd.	12,000	2.15
The Awa Bank, Limited	10,970	1.96
SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	8,645	1.54
Japan Trustee Services Bank, Ltd. (Trust Account 9)	6,004	1.07
Toho Holdings Co., Ltd.	5,670	1.01

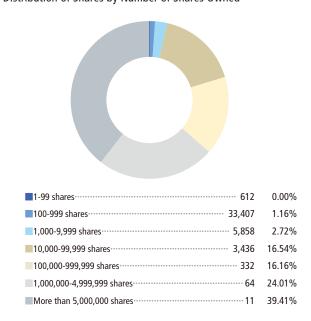
Notes

# Stock distribution

Distribution of Shares by Type of Shareholder



Distribution of Shares by Number of Shares Owned



Disclaimer

This annual report summarizes the operating and financial results of Otsuka Holdings Co., Ltd. and its subsidiaries and affiliates for fiscal 2011 (April 1, 2011 to March 31, 2012). It also includes information regarding selected material events which occurred between April 1, 2012 and the date of publication. This annual report contains forward-looking statements pertaining to plans, projections, strategies, and prospects for the Otsuka Group. These statements are based upon current analysis and belief in light of the information available on the issuing date of this annual report. As such, actual results may differ subject to risks and uncertainties that may affect Otsuka Group operations.

Note: The information regarding pharmaceutical products (including products under development) is not intended for any kind of advertising, promotion or medical advice.

<sup>1)</sup> Holdings of less than one thousand are rounded down.

<sup>2)</sup> For the purpose of calculating the percentage of voting rights, treasury stock (3,978 shares) has been excluded.







