

# ANNUAL REPORT 2014

For the year ended March 31, 2014



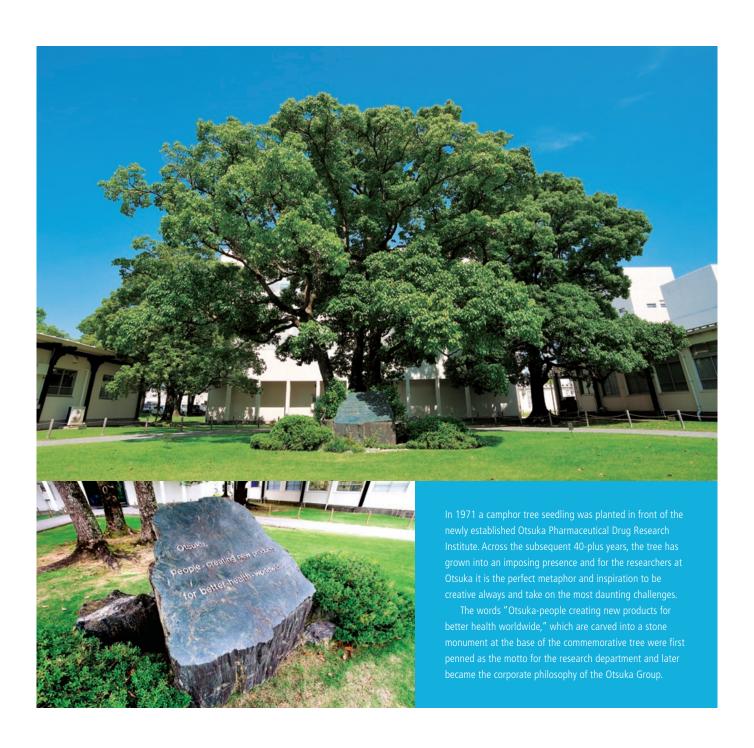
Otsuka-people creating new products for better health worldwide





# "JISSHO" (Proof through Execution) and "SOZOSEI" (Creativity)

The Otsuka Group is a global healthcare group operating under the corporate philosophy of "Otsuka-people creating new products for better health worldwide." 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 26 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.



#### Contents

- 02 Message from the President
- **03** The Otsuka Group's Business Model
- **04** Financial Highlights
- **05** Business Segments
- **06** Group Structure & Overview of Main Operating Companies
- 08 Otsuka Group Business Expansion
- 10 History

- 14 Review of the First Medium-Term Management Plan
- 16 Pharmaceutical Segment
- 28 Nutraceutical Segment
- **36** Consumer Products Segment / Other Segment
- 38 Group Companies
- 40 Global Operations
- 43 Corporate Governance

- 46 Social Responsibility
- 50 Financial Review
- **56** Consolidated Financial Statements
- **61** Notes to Consolidated Financial Statements
- 82 Independent Auditor's Report
- 83 Corporate Information
- 84 Shareholder Information

Fiscal 2013 was the last year of our First Medium-Term Management Plan. Its aim was to develop the Otsuka Group into a world-class global healthcare company. By defining the period for structural improvement, the plan enabled us to steadily implement priority measures and to secure revenue and profit growth.



In August 2014, we announced a Second Medium-Term Management Plan based on a framework of sustained investment and structural reform.

Under this plan, we will seek to secure greater revenue by diversifying the Otsuka Group's businesses while further capitalizing on our strengths. We will also take various measures to achieve the targets, overcoming the expiration of patents on one of our major products.

In keeping with our corporate philosophy, "Otsuka-people creating new products for better health worldwide," the Otsuka Group endeavors to create new and innovative products as well as new market categories in diverse areas related to health, devoted to better health worldwide.

We look forward to your ongoing support.

Tatsuo Higuchi

President and Representative Director, CEO

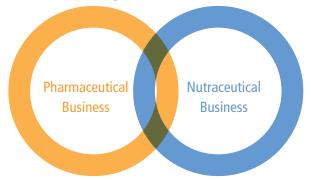
Otsuka Holdings Co., Ltd.

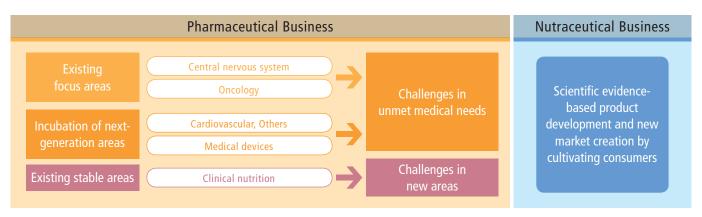
#### Global Expansion through Two Mainstay Businesses

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

The pharmaceutical business provides comprehensive support for human health to meet 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.

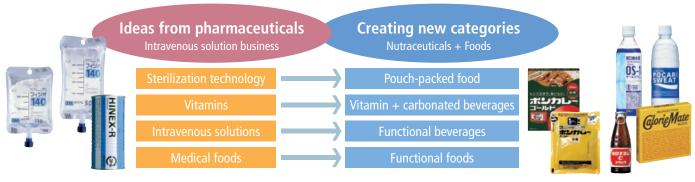


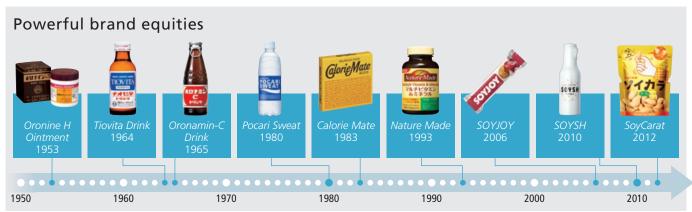


#### Synergy of Pharmaceuticals and Nutraceuticals

Otsuka develops products by leveraging its 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.



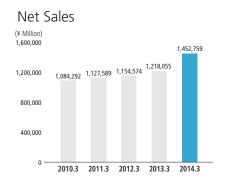


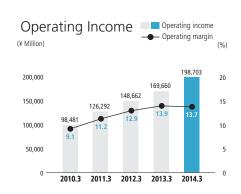


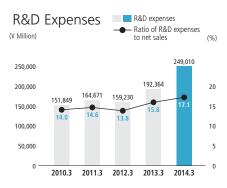
			Millions of U.S. dollars (Note 1)			
	<b>2010.3</b> (FY2009)	<b>2011.3</b> (FY2010) (Notes 3 and 4)	<b>2012.3</b> (FY2011)	<b>2013.3</b> (FY2012)	<b>2014.3</b> (FY2013)	<b>2014.3</b> (FY2013)
Net sales	¥1,084,292	¥1,127,589	¥1,154,574	¥1,218,055	¥1,452,759	\$14,115
Operating income	98,481	126,292	148,662	169,660	198,703	1,931
Net income	67,443	82,370	92,174	122,429	150,990	1,467
Per share of common stock-basic (Yen and U.S. dollars)	143.51	164.52	165.20	221.90	278.07	2.70
Dividends per share (Yen and U.S. dollars)	12.50	28.00	45.00	58.00	65.00	0.63
Capital expenditures	62,456	44,793	43,302	63,256	178,984	1,739
Depreciation and amortization	46,626	48,097	48,062	45,463	49,746	483
R&D expenses	151,849	164,671	159,230	192,364	249,010	2,419
Total assets	1,458,376	1,589,717	1,666,767	1,779,208	2,028,400	19,709
Net assets (Note 2)	948,457	1,163,326	1,222,765	1,325,071	1,510,760	14,679
Return on equity	7.7%	7.9%	7.8%	9.7%	10.8%	10.8%
Equity ratio	64.2%	72.4%	72.5%	73.7%	73.2%	73.2%
Number of shares issued	519,156,817	557,835,617	557,835,617	557,835,617	557,835,617	557,835,617
Number of employees	24,589	25,188	24,595	25,330	28,288	28,288

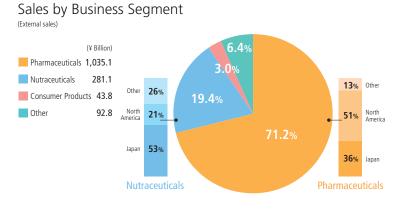
#### Notes:

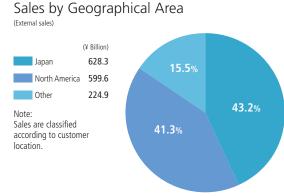
- 1. Financial information in U.S. dollars has been converted at US\$1=\$102.92, the rate as of March 31, 2014.
- 2. Minority interests have been included in net assets.
- 3. Effective from FY2010, the Company applied "Accounting Standard for Earnings Per Share" (ASBJ Statement No.2 revised on June 30, 2010), "Guidance on Accounting Standard for Earnings Per Share" (ASBJ 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). 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 upfront 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.







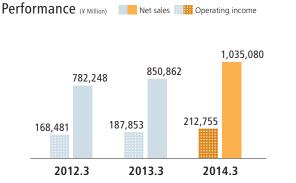




#### BUSINESS SEGMENTS

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

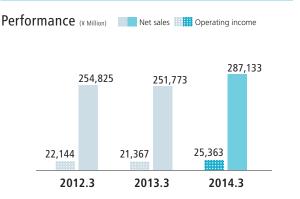
#### Pharmaceuticals



Our comprehensive approach to pharmaceutical research and development ranges from diagnosis to treatment of diseases targeted at unmet medical needs.

Pharmaceuticals / Clinical nutrition / Diagnostics / Medical devices

#### **Nutraceuticals**

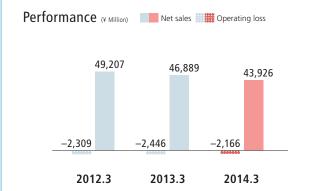


Expertise developed through our pharmaceuticals business is applied to the research and development of products that aid in the maintenance and improvement of day-to-day well-being.

Functional foods and beverages /
Cosmedics\* / OTC products, Quasi-drugs

\* Cosmetics + medicine

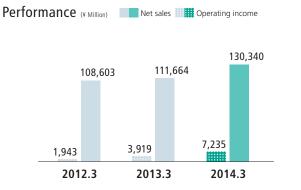
#### **Consumer Products**



The Otsuka Group is engaged in the research and development of original and unique products in the food and beverage field.

Beverages / Foods / Alcoholic beverages

#### Other

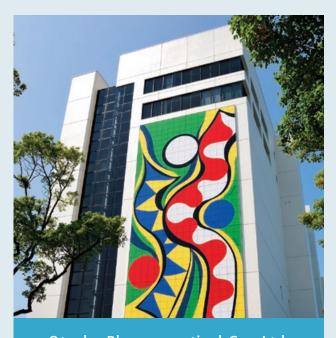


This segment covers a wide range of businesses from chemical products to electronic equipment.

Specialty chemicals / Fine chemicals / Distribution / Packaging / Electronic equipment

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.

Established in 1964, Otsuka Pharmaceutical is a total healthcare company. In keeping with its corporate philosophy of "Otsuka-people creating new products for better health worldwide," the company aims to care for people's overall health not only by treating illness, but also by sustaining day-to-day well-being. Otsuka Pharmaceutical operates a pharmaceutical business providing therapeutic drugs, as well as a nutraceutical business providing products that help people lead healthier and more active lives.



Taiho Pharmaceutical Co., Ltd.

Established in 1963, Taiho Pharmaceutical is a pioneer in the field of oral anticancer agents and is known in Japan as "Taiho, the anticancer drug maker." The company has also developed unique and novel drugs in the fields of allergy, immunology, and urology. In the consumer healthcare field, Taiho Pharmaceutical's product brands have been loved by consumers for decades. Based on its corporate philosophy, "We strive to improve human health and contribute to a society enriched by smiles," Taiho Pharmaceutical aspires to be an agile specialty pharmaceutical company that is trusted the world over.



#### Otsuka Pharmaceutical Factory, Inc.

Founded in 1921, Otsuka Pharmaceutical Factory is the original company of the Otsuka Group. The company meets a wide range of needs with its innovative products, including intravenous solutions, rehydration beverages, and medical foods. It also operates a consignment business that makes use of proprietary intravenous solution technologies. The company is tackling the development of global markets, especially in Asia. With the aim of being the best partner for people worldwide in the field of clinical nutrition, the company constantly seeks to take on new challenges. Otsuka Pharmaceutical Factory will continue to deliver a stable supply of safe, high-quality products to patients and healthcare professionals.



Otsuka Warehouse Co., Ltd.

In addition to providing product storage and logistics within the Group, Otsuka Warehouse distributes products to market for the Otsuka Group as well as for other firms. In recent years, the company's strategy has been to promote a common distribution platform for the three product areas of pharmaceuticals, food and beverages, and daily necessities. By forming partnerships with firms such as a leading instant noodle manufacturer and a beverage maker, Otsuka Warehouse has increased the percentage of its non-Group sales to about 50%. As a result of these efforts, the company received the Logistics Grand Prize (Management Innovation Award) in 2013, the most prestigious accolade in the Japanese logistics industry.



#### Otsuka Chemical Co., Ltd.

Otsuka Chemical has developed a range of businesses since 1950. These include operations in hydrazine-related business such as foaming agents, a fine chemicals business such as pharmaceutical intermediates, and a materials business that supplies titanate and engineering plastics compounds. Its corporate philosophy is, "Trusted by individuals, Trusted by the company, Trust is the dream of our society. Building trust with technology and commitment. Spreading trust with the people around the world." True to this philosophy, Otsuka Chemical is working creatively with customers to realize the full potential of chemical materials.



Otsuka Medical Devices Co., Ltd.

Otsuka Medical Devices was established in 2011 to oversee the Otsuka Group's medical device businesses. One such enterprise is JIMRO, which manufactures and sells *Adacolumn*, an apheresis device for granulocyte adsorption in inflammatory bowel disease. Other businesses include Achieva Medical and Microport Scientific, both located in Shanghai, China, as well as Era Endoscopy based in Pisa, Italy. Then there is KiSCO, which focuses on orthopedic implant devices for spinal disease. Otsuka Medical Devices is expanding its businesses globally and aspires to become one of the Group's core businesses.

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

Commenced chemical raw material business at Otsuka Pharmaceutical Factory, Inc.

Established Otsuka Chemical Co., Ltd.

Established Otsuka Foods Co., Ltd.

Established Otsuka Warehouse Co., Ltd.

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

Established Taiho Pharmaceutical

1964 Established

Otsuka Pharmaceutical

Undertook overseas business development in the U.S. and Thailand

Established P.T. Otsuka Indonesia and Taiwan Otsuka Pharmaceutical

#### History of product development

1964

Launched

Tiovita Drink



1968 Launched

Bon Curry



1983

Launched Calorie Mate



1990

Launched Mucosta



1953

Launched Oronine H **Ointment** 



1965

Launched Oronamin C Drink



1980

Launched Pocari Sweat



1988 Launched

Pletal



1946

Entered pharmaceutical business (intravenous solutions)

1980 Launched

Mikelan and Meptin



Launched

86

87

#### History of M&A and alliances

65

69

- \*1: Crystal Geyser Water Company
- \*2: Bristol-Myers Squibb Company
- \*3: American Biosciences (now Celgene) \*4: PDL BioPharma
- \*5: Nutrition & Santé

30 40 50

1900

1989 Acquired Pharmavite

Acquired Crystal Geyser\*1

1999

Signed a co-development and co-commercialization agreement for ABILIFY with BMS\*2 (U.S. and EU)

2000-

84 85

82 83

80

81

- 2004 Signed a licensing agreement for Aloxi with Helsinn Healthcare (Japan)
  - Acquired a stake in MicroPort Medical

- 2005 Acquired a stake in VV Food & Beverage and expanded SOYJOY business in China
  - Signed a licensing agreement for Abraxane with ABI\*3 (Japan)

#### International business development phase

#### **Expansion phase**

Started aggressive global expansion

Pursuing further global growth

Established

Established Arab Otsuka Pharmaceutical SAE 1981

Established China Otsuka Pharmaceutical Co., Ltd. 1982

Established Korea Otsuka Pharmaceutical Co., Ltd. 1988

Established Otsuka Pakistan Ltd. 1993

Established Guangdong Otsuka Pharmaceutical Co., Ltd. 1998

Established Otsuka Pharmaceutical Europe Ltd. 2008

Established Otsuka Holdings Co., Ltd. 2010

Public listing of the Company's shares 2011 Established

Otsuka Medical Devices

Sales | Pharmaceuticals Nutraceuticals, Consumer Products 2010 2012 2013 · DOT-JUNETIS Launched SOYSH and Launched Launched Launched SOYSH Gerblé (Japan) Abilify SoyCarat Lonsurf Maintena 1993 2002 2006 Launched Launched Launched Nature Made **ABILIFY** SOYJOY (Japan) 1999 Launched TS-1 80 96 97 98 99 00 01 02 03 04 05 06 07 91 93 94 95 09 10 11 12

2007 • Acquired all business rights to IV Busulfex from PDL\*4

2008 Acquired a stake in major mineral water company, ALMA Signed a co-development and co-commercialization agreement for *E Keppra* with UCB (Japan)

Signed a co-development and co-commercialization agreement for *Sprycel* and *Ixempra* with BMS (Global)

 Extended the co-development and co-commercialization agreement for ABILIFY with BMS (U.S.)

Acquired N&S\*5

2011

2010-

Acquired KiSCO group, thereby entering the orthopedic field

 Signed an alliance agreement with Lundbeck in the central nervous system field (Global)

Acquired a stake in Era Endoscopy, entering the endoscopic business

2012 Entered into business alliance for medical endoscope business with Pioneer

Acquired Valpiform

2013 Acquired Astex

Acquired a stake in Claris Otsuka



#### Founding of the Otsuka Group

The origin of the Otsuka Group goes back to 1921, when it started as a chemical raw material manufacturer in Naruto, Tokushima Prefecture, Japan, making magnesium carbonate from the liquid (called "bittern") that is left over after taking the salt out of seawater. In the early Meiji Period (late 19th century), Tokushima was one of Japan's ten largest cities. In addition to Japan's largest indigo industry, the city boasted secondary industries such as pharmaceutical and salt production. It also had prosperous agriculture, forestry, and fishing industries. In those days, with the modernization of Japan, entrepreneurial businesses began to spring up all over the country. In the Seto Inland Sea area (including Tokushima), an industry emerged that made effective use of bittern from the area's natural seawater, and many companies in Tokushima began to manufacture products to meet the demand of Japan's newly emerging industries.

#### Maker of Chemical Raw Materials

The Company's products were mostly pharmacopeia raw materials. The calligraphic work below shows the company motto in Japanese, written by the founder, Busaburo Otsuka. It has formed the foundation of Otsuka's product creation up to the present day and this commitment to product quality remains vital to the Otsuka Group. The Group's business grew steadily as a raw material manufacturer due to pharmacopoeia raw material diversification and the Company's designation as a military-supply factory.



# 君はる場合は今日

"Quality is the lifeblood of the factory. Packaging is a part of quality. Always make and sell products from the stand point of the customer."

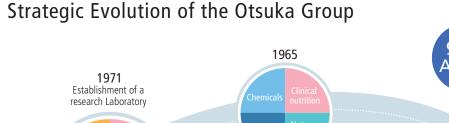
Busaburo Otsuka, founder of the Otsuka Group

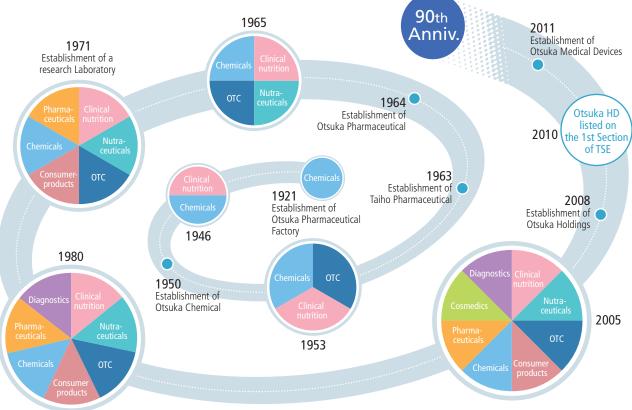
#### **Expanding to Become a Product Manufacturer**

The Otsuka Group entered the pharmaceutical business in 1946 by introducing a series of new intravenous solution products and expanded its business to all of Japan. The Group's business grew through development and improvement of product containers, introduction of the most advanced equipment from overseas and product export.

#### **Establishing Group Companies**

The Otsuka Group accumulated technical know-how in the production of intravenous solutions and chemical products and continued to diversify. In 1953, the Company launched its first over-the-counter medicine, *Oronine Ointment*, which remains popular even today. Then it took on the challenge of the energy drink market, and came out with a successful product, *ORONAMIN C DRINK*, in 1965. The main business areas of the Otsuka Group today—chemical raw materials, intravenous solutions, prescription drugs and over-the-counter products, and health and soft drinks—took shape in the 1950s and 1960s. In order to strengthen the diversification of the business, a series of Group companies was established.





The Otsuka Group Moves into the **Future** 

In 2008, the Otsuka Group reorganized itself by establishing Otsuka Holdings. In 2010, Otsuka Holdings was listed on the First Section of the Tokyo Stock Exchange, beginning a new chapter in the Otsuka Group's history. The Otsuka Group's corporate philosophy, "Otsukapeople creating new products for better health worldwide," is a guiding principle for all Otsuka employees.

Alongside its focus on pharmaceuticals and nutraceuticals as its two mainstay businesses, the Group has retained its original chemical business and added new business areas such as medical devices, thus continuing to confront challenges globally.

The Otsuka Group's history is also recounted on the Otsuka Holdings website.

http://www.otsuka.com/en/enkaku/



# The Secret Story of Calorie Mate



In 1946, the World Health Organization declared that "Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity." Viewing nutrition as a driving power for a healthy life, Otsuka Pharmaceutical started development of enteral nutrition products used in clinical settings in 1977. The concept took its inspiration from the food used in space flights. Aiming for a product that was easy to put in the mouth, had a palatable flavor, and provided the specified nutrients and calories with each mouthful, the Company created *Hinex-R*, the predecessor of *Calorie Mate CAN*, in 1979. The original concept for *Calorie Mate BLOCK*, on the other hand, was an easy breakfast to enjoy when a person does not have a good appetite. Starting from this idea, the Company pursued product universality—a food that could be consumed by anyone, anywhere, anytime. It aimed to develop a nutrition product that would regulate the physical condition with a combination of useful nutrients suited to various life scenes, ranging from sports to dieting.

This is how *Calorie Mate CAN* and *Calorie Mate BLOCK*, although developed separately, were rolled out under the same brand, appealing to the need for balanced nutrition.

The composition of *Hinex-R* was established based on an investigation of the nutritional requirements of the Japanese and the medical foods used at hospitals. Revamped as a nutrition product for general consumers through numerous cycles of trial and error, including processes to achieve a uniform mixture of the various ingredients, long-term stability, and the maintenance of flavor under high-temperature sterilization, it became *Calorie Mate CAN*. Likewise, *Calorie Mate BLOCK* went through various prototypes, including health food types, sports types, and diet types as well as medical types before settling down as a block of shortbread with 100 kilocalories.







The Company faced an uphill battle to spread the unprecedented product concept of a nutritionally balanced food among consumers. When the products were initially launched, the conventional understanding was that juice is sweet and snacks are an indulgence. Accordingly, Otsuka Pharmaceutical decided to target athletes in its promotion.

Calorie Mate established its position as a popular food among athletes, who are concerned with performance, by emphasizing to them the importance of nutrition and thereby gaining their understanding of the product concept. Subsequently, the nutritional balance and convenience of Calorie Mate went on to find recognition not only among athletes but also among general consumers in various situations, including as a nutritionally balanced and calorie-controlled food for dieting, as a breakfast for busy office workers, and as an emergency food during disasters.

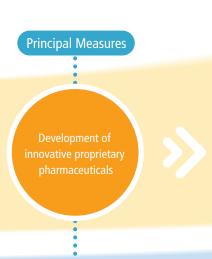


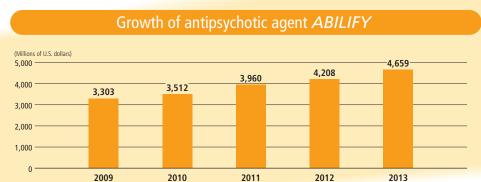
Today, 30 years since the launch of *Calorie Mate*, Otsuka Pharmaceutical is continuing its daily research efforts to add further value to the product. The Company's Saga Nutraceuticals Research Institute overturned the conventional notion that just getting sugar would help people think better, discovering the new truth that nutritional balance, not just sugar, is the key to engaging the brain.\* Committed to upholding Otsuka Group's corporate philosophy of "Otsuka-people creating new products for better health worldwide," Otsuka Pharmaceutical is determined to carry on with product development and the continued promotion of the value of *Calorie Mate*, in order to ensure that the product remains a balanced nutritional food that can contribute to people's health.

\*: Higuchi, et al. Journal of the Japanese Society of Clinical Nutrition, 2007.









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



Increase overseas sales of *Pocari Sweat* and other global products

Increase sales by creating new markets with new products

Reduction of production costs and optimization of expenditure

Balanced allocation of resources for creating new markets

Next-generation business incubation hrough strategic alliances and other measures



#### Alliance with H·Lundbeck A/S

As part of the effort to implement the measures in the First Medium-Term Management Plan, Otsuka Pharmaceutical signed a global alliance agreement in the area of the central nervous system in November 2011 with Danish company Lundbeck, a global leader in the field.



#### First Medium-Term Management Plan Performance: Targets and Results

Item	FY2013 Target of the Medium-Term Management Plan	FY2013 (Actual)	Percentage of Achievement
Net sales (Billions of yen)	1,330.0	1,452.8	109.2%
R&D expenses (Billions of yen)	200.0	249.0	124.5%
Operating income (Billions of yen)	200.0	198.7	99.4%
Net income (Billions of yen)	130.0	151.0	116.2%
Earnings per share (Yen)	230	278.07	120.9%
Return on equity	10% or more	10.80%	Achieved



#### Development of innovative new pharmaceuticals

#### Abilify Maintena

For the indication of maintenance treatment of schizophrenia:

- March 2013: Launched in the U.S.
- January 2014: Launched in Europe
- January 2014: Manufacture and marketing approval filed for in Japan

Cardiovascular system

#### Samsca (tolvaptan)

For the indication of treatment of autosomal

- December 2013: Additional indication filed for in Europe
- March 2014: Approved for the additional indication in Japan
- Phase 3 clinical trial ongoing in the U.S.



#### Lonsurf (TAS-102)

 May 2014: Launched in Japan for the indication of unresectable advanced or recurrent colorectal cancer (only if refractory to standard therapies)



Refer to P26 Feature 2

dominant polycystic kidney disease (ADPKD):



#### Deltyba (delamanid)

For the indication of treatment of multidrug-resistant tuberculosis:

- April 2014: Approved in Europe
- July 2014: Approved in Japan



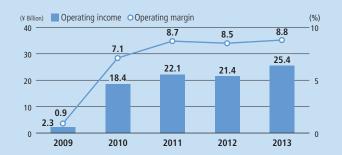
Refer to P24 Feature 1

Refer to P24 Feature 1

#### Sales Increase through Market Expansion and Profit Growth through Cost Structure Review

Profit improvement (operating margin)

0.9% >> 8.8%



#### Profit structure improvement in Japan

- Increase sales by fostering newly developed products
- Suitably control expenses

#### Expand the share of high-profitability overseas sales

 Increase the share of overseas sales by 6 percentage points through high overseas sales growth rate







#### **Progress Since Signing of** Agreement with Lundbeck

#### March 2013

Abilify Maintena was launched in the U.S. and co-promotion was started

Lundbeck agreed to co-develop and co-commercialize the new compound Lu AE58054 under development as a treatment for Alzheimer's disease

Co-promotion of ABILIFY was started in Europe

#### November 2013

Abilify Maintena was approved in Europe

Abilify Maintena was launched in the UK and co-promotion started

Result of Phase 3 trial on brexpiprazole for treatment of major depressive disorder was presented at the European Psychiatry Association Conference

#### Acquisition of Astex Pharmaceuticals Inc.

In October 2013, Otsuka Pharmaceutical acquired the U.S. company Astex through its wholly owned subsidiary Otsuka America, Inc. Astex's current oncology pipeline and its fragment-based drug discovery technology will strengthen not only Otsuka Pharmaceutical's development portfolio, but also its research capabilities in next-generation drug discovery in oncology, the central nervous system and other therapeutic areas.



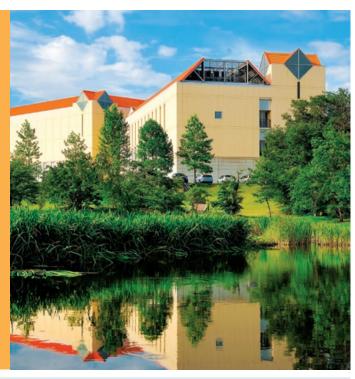






#### Pharmaceutical Segment Overview

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.



Therapeutic drugs

Central nervous system, Oncology, Cardiovascular system, Gastroenterology, Respiratory system, Infectious disease, Ophthalmology, Dermatology, Allergies, Urology, Other areas

Clinical nutrition

Intravenous solutions, Enteral nutrition, Contract manufacturing

Diagnostics

Influenza diagnostic agents, Helicobacter pylori test kit, Other products

Medical devices

Apheresis device for leukocyte adsorption, Drug-eluting stents, Spinal devices, Other products

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), major depression (adjunctive)	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
SAMSCA (tolvaptan)	Vasopressin V <sub>2</sub> -receptor antagonist	Hyponatremia, cardiac edema, hepatic edema, autosomal dominant polycystic kidney disease (ADPKD)	Otsuka Pharmaceutical
E Keppra (levetiracetam)	Antiepileptic	Adjunctive therapy in the treatment of partial onset seizures, with or without secondary generalisation, in patients with epilepsy	Otsuka Pharmaceutical
TS-1 (tegafur, gimeracil, oteracil )	Antimetabolite	Gastric cancer, colorectal cancer, head and neck cancer, non-small cell lung cancer, inoperable or recurrent breast cancer, pancreatic cancer, biliary tract cancer	Taiho Pharmaceutical
Aloxi (palonosetron)	5-HT₃ receptor antagonist antiemetic agent	Digestive symptoms (nausea and vomiting) (including delayed phase) following administration of antineoplastic agents (cisplatin, etc)	Taiho Pharmaceutical
Abraxane (paclitaxel protein-bound particles for injectable suspension)	Anti-cancer	Breast cancer, gastric cancer, non-small cell lung cancer	Taiho Pharmaceutical
Lonsurf (trifluridine and tipiracil )	Anti-cancer	Unresectable advanced or recurrent colorectal cancer (only if refractory to standard therapies)	Taiho Pharmaceutical
ELNEOPA (high-calorie TPN solution, containing glucose, electrolytes, amino acids, vitamins, and trace elements)	High-calorie TPN solution	Replenishment of liquids, electrolytes, calories, amino acids, vitamins, zinc, iron, copper, manganese, and iodine by intravenous infusion for management of nutritional requirements in patients unable to obtain adequate oral or enteric nutritional support	Otsuka Pharmaceutical Factory

#### Therapeutic Drug Business

#### **Central Nervous System**

In the area of central nervous system (CNS) disorders, global sales of atypical antipsychotic agent ABILIFY rose 30% year on year on a yen basis. The drug was also ranked seventh\*1 in global drug sales. In the U.S., an increase in ABILIFY prescriptions for adjunctive therapy in major depressive disorder and for bipolar disorder, as well as price increases, supported double-digit growth in sales on a local currency basis compared with the previous fiscal year. ABILIFY also became the best-selling drug\*2 in the U.S. in Jan-Dec 2013. In Europe, Otsuka Pharmaceutical Co., Ltd. (Otsuka Pharmaceutical), a wholly owned subsidiary of the Company, and H. Lundbeck A/S (Lundbeck) began collaborating on sales of ABILIFY in April 2013. Sales of ABILIFY grew significantly, mainly due to an increase in prescriptions for the treatment of manic episodes in bipolar disorder. In Asia, sales of ABILIFY continued to expand, mainly supported by an increase in prescriptions for adjunctive therapy in major depressive disorder and for pediatric indications, such as Tourette disorder, in South Korea. In Japan, ABILIFY became the first atypical antipsychotic agent to be approved for the additional indication of major depressive disorder in June 2013. This additional indication and growth in prescriptions for orally disintegrating tablets supported double-digit sales growth compared with the previous fiscal year.



As part of our global alliance with Lundbeck, including the development of five compounds\*3, both companies began sales of *Abilify Maintena*, an aripiprazole intramuscular depot formulation (once-monthly injection), in the U.S. in March 2013 for maintenance treatment of schizophrenia. Prescriptions of the drug, the first to be developed as part of the global alliance, have been growing steadily due to recognition of the drug's good safety and tolerability. In Europe, *Abilify Maintena* received marketing approval from the European Commission for maintenance treatment of schizophrenia in November 2013. As of the end of May 2014, the drug was on sale in the U.K. and five other European countries.

In addition to our global alliance, Otsuka Pharmaceutical and Lundbeck agreed in October 2013 to collaborate on developing and

commercializing *nalmefene* in Japan. *Nalmefene*, which is based on a new therapeutic concept, is indicated for the reduction of alcohol consumption. In December 2013, the two companies also signed an agreement to collaborate on the development of *Lu AF20513*, an Alzheimer's disease vaccine.

In Japan, antiepileptic drug *E Keppra*, co-promoted with UCB Japan, was approved for the treatment of children aged four years and older (additional pediatric indication and dosage) in May 2013. In addition, *E Keppra Dry Syrup 50%* was launched in August 2013, aimed at patients who have difficulty swallowing tablets. These factors led to strong growth in domestic sales compared to the previous fiscal year. *Neupro Patch*, the world's only transdermal dopamine agonist helping to maintain stable blood concentration levels of the drug for 24 hours, registered steady growth in prescriptions for the treatment of Parkinson's disease.

As part of our CNS efforts, Otsuka Pharmaceutical and IBM concluded a strategic alliance in March 2014 that brings together the two companies' specialist expertise, technologies and know-how. Through a global collaboration, the partners plan to develop care coordination solutions that improve medical service provision and contribute to the treatment and care outcomes of patients with mental health conditions.

#### Cardiovascular System

In the area of cardiovascular disorders, global sales of *Samsca*, a first-in-class vasopressin V<sub>2</sub>-receptor antagonist available in 20 markets worldwide, increased by more than 60% year on year. This increase was supported by the drug's growing acceptance among medical specialists due to the new value it brings to clinical practice and because of its formulation as an oral aquaretic agent. In Japan, *Samsca* 7.5mg tablets were launched as a new formulation in June 2013.



Samsca was also granted an additional indication for the treatment of fluid retention in patients with hepatic cirrhosis in September 2013. In March 2014, Samsca was further approved in Japan for the additional indication of suppressing the progression of autosomal dominant polycystic kidney disease (ADPKD) followed by Samsca 30mg tablets launch in May 2014, becoming the world's first drug therapy for this condition. The Group is working to grow the value of Samsca through continuing education of physicians with regard to the drug's safety profile and optimal usage in the clinical setting. The antiplatelet agent Pletaal/Pletal is viewed positively by domestic medical practitioners as a convenient orally disintegrating tablet for patients following cerebral infarction. However, sales of the drug were affected by generics in Japan, with domestic sales declining year on year. Overseas sales of Pletaal/Pletal increased year on year, supported mainly by sales growth in South Korea.

#### Oncology

In the area of oncology, TS-1 Combination OD Tablets T20, T25 were launched as an additional formulation of the anti-cancer agent TS-1 in Japan in June 2013. Also, sales promotions utilizing evidence-based medicine helped raise awareness of the drug as a treatment for colorectal cancer, head and neck cancer and pancreatic cancer, supporting stable sales. Overseas, TS-1 is gradually being rolled out in Europe and is now (as of March 31, 2014) available in 27 countries worldwide. Sales of the anti-cancer agent UFT and the reduced folic acid formulation Uzel both declined year on year. Sales of Aloxi, a long-acting 5-HT<sub>3</sub> receptor antagonist antiemetic agent, were higher, supported by steady growth in prescriptions, while sales of the anti-cancer agent Abraxane expanded significantly year on year, supported by its approval for the additional indications of gastric cancer and non-small cell lung cancer in February 2013. Lonsurf, an anti-cancer agent with a new mechanism of action was approved in Japan for the treatment of unresectable advanced or recurrent colorectal cancer (only if refractory to standard therapies) in March and launched in May 2014, first in the world.

Revenues from the anti-cancer agent *SPRYCEL*, which is being co-promoted in Japan, the U.S. and Europe with BMS\*<sup>4</sup>, increased sharply due to the drug's increasing global sales as a first-line treatment for chronic myeloid leukemia and due to an increase in our sales-based revenue quota starting from January 2013. *Busulfex*, which is the only allogeneic hematopoietic stem cell pre-transplanting regimen approved by the U.S. Food and Drug Administration (FDA), is now sold by the Group and its partners in more than 50 countries. *Busulfex* has become established as the standard drug for use as a conditioning agent prior to bone marrow transplants in place of total-body radiation.

Otsuka Pharmaceutical took over sole responsibility for the promotion of *Busulfex* in Japan and Asia from April 2013, in addition

to the exclusive marketing rights the Group already owns for *Busulfex* in the U.S. and Canada. Also, in March 2014, Otsuka Pharmaceutical acquired the rights from Eisai Inc. of the U.S. to develop and sell the DNA methylation inhibitor *Dacogen* worldwide, excluding Mexico.

#### Other Areas

In other areas, sales of the antigastritis and antigastric ulcer agent *Mucosta* declined year on year due to generic competition, although steps were taken to strengthen the *Mucosta* brand, including the launch of tablets with the brand name printed on both front and back. In addition, Otsuka Pharmaceutical and Takeda Pharmaceutical Company Limited signed an agreement in March 2014 for the co-promotion of sales in Japan of TAK-438, a treatment for acid-related diseases. In the area of ophthalmology, prescriptions for dry eye treatment *Mucosta Ophthalmic Suspension UD 2%* grew steadily, supporting a large increase in sales compared with the previous fiscal year. *Deltyba*, an anti-tuberculosis agent with a novel mode of action, was approved for the treatment of multidrug-resistant tuberculosis (MDR-TB) in Europe in April and in Japan in July 2014 respectively.

#### **Global Operation**

To further strengthen the global development of the Group's pharmaceutical operations, Otsuka Pharmaceutical established Otsuka Europe Development and Commercialisation Ltd. (OEDC) in the suburbs of London, in July 2013 as its new European center for the clinical development of pharmaceuticals. In October 2013, Otsuka Pharmaceutical acquired Astex Pharmaceuticals, Inc. (Astex) of the U.S. through its wholly owned subsidiary Otsuka America, Inc. Astex's current oncology pipeline and its fragment-based drug discovery technology will strengthen not only Otsuka Pharmaceutical's development portfolio, but also its research capabilities in nextgeneration drug discovery in CNS and other therapeutic areas. In July 2013, Otsuka Pharmaceutical Factory, Inc. acquired a stake in Claris Otsuka Limited (Claris Otsuka), based in Ahmedabad, India.

<sup>\*1: © 2014</sup> IMS Health. All rights reserved. Estimated based on "World Review Preview 2013 (Year 2013 Sales Data)." Reprinted with permission.

<sup>\*2: © 2014</sup> IMS Health. All rights reserved. Estimated based on "MIDAS Quantum 4Q/2013 Sales Data." Reprinted with permission.

<sup>\*3:</sup> Abilify Maintena, brexpiprazole, Lu AE58054 and two new compounds currently being researched and developed by Lundbeck.

<sup>\*4:</sup> Bristol-Myers Squibb Company

#### **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." This business includes Japan's first plastic bottles utilizing advanced sterilization technology, dual-chamber bags for the administration of high-calorie infusion solutions, and kits for aseptic delivery of antibiotic solutions. It also includes four-chamber bags providing sterile, effective solutions that deliver outstanding ease of administration. In fiscal 2013, the high-calorie TPN solution *ELNEOPA*, which is a core product in this business, gradually increased its share of sales in Japan through expanded use and adoption in medical facilities and the home



care market. The company launched the plasma substitute *Voluven 6%* intravenous solution, meeting the stated wish of many medical professionals. It was introduced into the market quickly, focusing on anesthesiology. Substantial synergy was obtained with an awareness-raising campaign that featured *Voluven* in combined use with *Bicanate Injection* or *Physio 140 Injection*. This business supports the parenteral nutrition needs of patients by offering a full lineup of products with outstanding quality to meet the needs of physicians.

The company also operates an intravenous solutions business in international markets as well as in Japan, with production bases in eight\*5 other countries, mainly in Asia.

\*5: Including affiliates accounted for by the equity method and unconsolidated companies

#### **Diagnostics Business**

#### Core products

Brand name	Category	Company
UBIT	Diagnostic agent for <i>H. pylori</i>	Otsuka Pharmaceutical
WT1 mRNA Assay Kit II "Otsuka"	Wilms tumor-1 gene (WT1) mRNA measurement KIT	Otsuka Pharmaceutical
Quick Navi-Flu	Influenza virus test kit	Otsuka Pharmaceutical



The diagnostics business focuses on the development and sale of intracorporeal and extracorporeal diagnostic agents for clinical use and research-use reagents.

There was a significant growth in demand for *in vitro* diagnostic agents in the field of infectious diseases, and for the *WT1 mRNA Assay Kit II* "Otsuka" in the blood oncology field, while *Quick Navi-Flu* influenza virus test kits also saw increased demand. This contributed to the growth of the business as a whole.





#### Medical Devices Business

#### Core products

Brand name	Category	Company
Adacolumn	Apheresis device for leukocyte adsorption	JIMRO
SUIREN	Pedicle screw system	KiSCO





Otsuka Medical Devices was established in 2011 to oversee the Otsuka Group's medical equipment business. Its purpose is to develop total healthcare in the Group's core business outside of pharmaceuticals and nutraceuticals.

Its subsidiary JIMRO manufactures and markets *Adacolumn*, an apheresis device for granulocyte adsorption used to treat inflammatory bowel disease and intractable skin disease.

In the field of orthopedics, KiSCO globally sells orthopedic implant devices for injuries and spinal disease. Other major affiliates include Microport Scientific Corporation (fields including cardiovascular disease and artificial joints) and Achieva Medical (Shanghai) Co., Ltd. (cerebral vascular field), both in Shanghai, China, and Era Endoscopy S.r.l. (self-propelling robotic colonoscopy) in Pisa, Italy.

### Pipeline Information (as of June 30, 2014)

Code / <brand name=""></brand>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development s	tatus	
Central ner	vous system							
				Schizophrenia / Depot injection	JP			
OPC-14597				Autism / Oral	JP			
<abilify></abilify>	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Tourette's disorder / Tablet	US			
<abilify maintena="">: Depot injection</abilify>				Bipolar I / Depot injection	JP, US, EU			
				Agitation associated with dementia of the Alzheimer's type / Oral	JP			
				Epilepsy (generalized onsetseizures) / Oral	JP			
L059 <e keppra=""></e>	levetiracetam	UCB	Antiepileptic drug	Epilepsy (partial onset seizures) / injection	JP			
				Epilepsy (partial onset seizures / mono therapy) / Oral	JP			
				Adjunctive therapy for major depressive disorder / Oral	US, EU			
				Schizophrenia / Oral	JP, US, EU			
OPC-34712	brexpiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	ADHD (Adults) / Oral	US			
				Agitation associated with dementia of the Alzheimer's type / Oral	US, EU			
				Posttraumatic stress disorder (PTSD) / Oral	US, EU			
Lu AE58054		Lundbeck	selective serotonine 5-HT <sub>6</sub> receptor antagonist	Alzheimer's disease / Oral	US, EU			
ASC-01	aripirazole, sertraline	Otsuka Pharmaceutical	Dopamine partial agonist / Selective serotonin reuptake inhibitor	Major depressive disorder / Oral	JP, Asia			
Oncology								
ABI-007 <abraxane></abraxane>	paclitaxel protein-bound particles for injectable suspension	Celgene	Anti-cancer (nanoparticle)	Pancreatic cancer / Injection	JP			
				Gastric cancer / Oral	US			
S-1 <ts-1>Japan, Korea <teysuno>EU</teysuno></ts-1>	tegafur, gimeracil,	Teile Dhamasautical	0 - ai ( ai a - l l'ia-)	Uterocervical cancer / Oral	JP, Asia			
<愛斯万>China <愛斯萬>Taiwan <ts-one>Singapore</ts-one>	oteracil	Taiho Pharmaceutical Anti-cancer (anti-metabolite)	Anti-cancer (anti-metabolite)	Hepatocellular carcinoma / Oral	JP			
C13-ONE/Sillyapore				Renal cell carcinoma / Oral	JP			
TSU-68	orantinib	(Sugen)	Anti-cancer (molecular-targeted drug)	Hepatocellular carcinoma / Oral	JP, Asia			
TAS-102	authorishes atomosti	Taiho Pharmaceutical	Anti-cancer	Colorectal cancer / Oral	JP, US, EU, Asia			
<lonsurf></lonsurf>	trifluridine, tipiracil	Idillo Fildillidceutical	Anu-cancei	SCLC / Oral	JP, EU			
TAS-118	tegafur, gimeracil, oteracil, folinate	Taiho Pharmaceutical	Anti-cancer (anti-metabolite)	Pancreatic cancer / Oral	JP, Asia			
<sativex></sativex>	nabiximols	GW Pharmaceuticals	Cannabinoid (THC, CBD)	Cancer pain / Oral spray	US			
OCV-101		OncoTherapy Science	Therapeutic cancer vaccine	Pancreatic cancer / Injection	JP			
<sprycel></sprycel>	dasatinib	BMS	Anti-cancer (molecular-targeted drug)	Pancreatic cancer / Oral	US, EU			
				Ovarian cancer / Injection	US, EU			
SGI-110		Astex	Anti-cancer	Hepatocellular carcinoma / Injection	US, EU			
				Acute myeloid leukemia, Myelodys plastic syndrome / Injection	US			
AT13387		Astex	Anti-cancer (molecular-targeted drug)	Prostate cancer / Injection	US, EU			
7 ti 1990/		, SICA	And cancer (molecular-talgeted diug)	NSCLC / Injection	US, EU			
AT7519		Astex	Anti-cancer (molecular-targeted drug)	Multiple myeloma / Injection	US			



#### PHARMACEUTICAL SEGMENT

Otsuka-people creating new products for better health worldwide

Code / <brand name=""></brand>	Generic name	Origin	Category	Indication / Dosage form	Country / Region		Develo	pment st	atus	
ET-743	trabectedin	PharmaMar	Anti-cancer	Malignant soft tissue sarcoma / Injection	JP					
OPB-31121		Otsuka Pharmaceutical	Anti-cancer (molecular-targeted drug)	Anti-cancer / Oral	JP, Asia					
OPB-51602		Otsuka Pharmaceutical	Anti-cancer (molecular-targeted drug)	Anti-cancer / Oral	JP, US, Asia					
OPB-111077		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	US, Asia					
OPB-111001		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	EU					
TAS-114		Taiho Pharmaceutical	Anti-cancer (anti-tumor enhancer)	Solid tumors / Oral	JP, US, EU					
TAS-115		Taiho Pharmaceutical	Anti-cancer (molecular-targeted drug)	Solid tumors / Oral	JP					
TAS-116		Taiho Pharmaceutical	Anti-cancer (molecular-targeted drug)	Solid tumors / Oral	JP					
OCV-501		Otsuka Pharmaceutical	WT1 targeted cancer vaccine	Secondary prevention of elderly acute myeloid leukemia / Injection	JP, Asia					
OCV-C02		OncoTherapy Science	Therapeutic cancer vaccine	Colorectal cancer / Injection	JP					
OPC-12759	rebamipide	Otsuka Pharmaceutical	Oral mucosal protectant·mucosal healing agent	Stomatitis associated with cancer chemoradiotherapy / Solution	JP					
Cardiovascu	ılar		agent	etternoraalottietapy / Johanon		Phase I F	hase II P	hase III	Filed	Appro
				Hepatic edema / Oral	Asia					
				Autosomal dominant polycystic kidney	EU					
				disease / Oral	US					
OPC-41061 <samsca></samsca>	tolvaptan		Cardiac edema / Oral	Asia						
			Carcinomatous edema / Oral	JP						
			Volume overload in hemodialysis/ Oral	JP						
				Volume overload in peritoneal dialysis/ Oral	JP					
OPC-108459		Otsuka Pharmaceutical		Paroxysmal and persistent atrial fibrillation / Injection	JP, US					
Other areas				nomication, injection		Phase I F	hase II P	hase III	Filed	
YP-18 <zosyn></zosyn>	tazobactam, piperacillin	Taiho Pharmaceutical	Antibiotic agent	Febrile neutropenia / Injection	JP					
				Allergic rhinitis / Oral	JP					
TAC-202	bilastine	Faes Farma	Histamine H <sub>1</sub> antagonist	Chronic urticaria, Pruritus associated with skin disease/ Oral	JP		Phase II	/ III		
					EU					
OPC-67683 <deltyba></deltyba>	dalaman SI			Multidrug-resistant tuberculosis/ Oral						
	delamanid	Otsuka Pharmaceutical	Anti-tuberculosis agent		JP US		-			
,	delamanid	Otsuka Pharmaceutical	Anti-tuberculosis agent	Multidrug-resistant tuberculosis for	US EU					
OPC-12759E <mucosta< td=""><td>deiamanid rebamipide</td><td>Otsuka Pharmaceutical  Otsuka Pharmaceutical</td><td>Anti-tuberculosis agent  Mucin-production enhancing agent</td><td>,</td><td>US</td><td></td><td></td><td></td><td></td><td></td></mucosta<>	deiamanid rebamipide	Otsuka Pharmaceutical  Otsuka Pharmaceutical	Anti-tuberculosis agent  Mucin-production enhancing agent	,	US					
OPC-12759E <mucosta Ophthalmic Suspension&gt; OPB-2045G</mucosta 		Otsuka Pharmaceutical Otsuka Pharmaceutical	-	Multidrug-resistant tuberculosis for pediatrics / Oral	US EU JP					
OPC-12759E <mucosta Ophthalmic Suspension&gt;</mucosta 	rebamipide olanexidin Amino Acid, Carbohydrate, and Fat Emulsion Injection	Otsuka Pharmaceutical	Mucin-production enhancing agent	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)	US EU JP					
OPC-12759E <mucosta Ophthalmic Suspension&gt; OPB-2045G</mucosta 	rebamipide olanexidin Amino Acid, Carbohydrate,	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical	Mucin-production enhancing agent  Anti-septics	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/	US EU JP JP					
DPC-12759E <mucosta Dphthalmic Suspension&gt; DPB-2045G DPF-105 DPC-6535</mucosta 	rebamipide  olanexidin  Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory	Mucin-production enhancing agent Anti-septics Protein and amino acid preparation	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection	US EU JP JP		Phase III	o / III		
OPC-12759E <mucosta ophthalmic="" suspension=""> OPB-2045G OPF-105 OPC-6535 ACU-4429</mucosta>	rebamipide olanexidin Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins tetomilast	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory Otsuka Pharmaceutical	Mucin-production enhancing agent Anti-septics Protein and amino acid preparation Anti-inflammatory agent	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection  COPD / Oral	US EU JP JP JP	Phase I		o / III		
OPC-12759E <mucosta Ophthalmic Suspension&gt; OPB-2045G OPF-105</mucosta 	rebamipide olanexidin Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins tetomilast	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Acucela	Mucin-production enhancing agent Anti-septics  Protein and amino acid preparation  Anti-inflammatory agent  Visual cycle modulator  Adenosine A <sub>2a</sub> receptor agonist  β-adrenergic receptor blocker/	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection  COPD / Oral  Dry AMD / Oral	US EU JP JP JP US, Asia	Phase I		o / III		
OPC-12759E <mucosta ophthalmic="" suspension=""> OPB-2045G  OPF-105  OPC-6535  ACU-4429  OPA-6566</mucosta>	rebamipide  olanexidin  Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins tetomilast  emixustat	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Acucela Otsuka Pharmaceutical	Mucin-production enhancing agent  Anti-septics  Protein and amino acid preparation  Anti-inflammatory agent  Visual cycle modulator  Adenosine A <sub>2a</sub> receptor agonist	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection  COPD / Oral  Dry AMD / Oral  Glaucoma / Eye Drops	US EU JP JP JP US, Asia US	Phase I		o / III		
DPC-12759E <mucosta dphthalmic="" suspension=""> DPB-2045G  DPF-105  DPC-6535  ACU-4429  DPA-6566  DPC-1085EL  DPA-15406</mucosta>	rebamipide  olanexidin  Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins tetomilast  emixustat	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Acucela Otsuka Pharmaceutical	Mucin-production enhancing agent  Anti-septics  Protein and amino acid preparation  Anti-inflammatory agent  Visual cycle modulator  Adenosine $A_{2a}$ receptor agonist $\beta$ -adrenergic receptor blocker/ prostaglandine F2 $\alpha$ analogue	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection  COPD / Oral  Dry AMD / Oral  Glaucoma / Eye Drops  Glaucoma / Eye Drops	US EU JP JP JP US, Asia US US				Filed	Approx
DPC-12759E <mucosta dphthalmic="" suspension=""> DPB-2045G  DPF-105  DPC-6535  ACU-4429  DPA-6566  DPC-1085EL</mucosta>	rebamipide  olanexidin  Amino Acid, Carbohydrate, and Fat Emulsion Injection with Electrolytes and Vitamins tetomilast  emixustat	Otsuka Pharmaceutical Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Factory Otsuka Pharmaceutical Acucela Otsuka Pharmaceutical	Mucin-production enhancing agent  Anti-septics  Protein and amino acid preparation  Anti-inflammatory agent  Visual cycle modulator  Adenosine $A_{2a}$ receptor agonist $\beta$ -adrenergic receptor blocker/ prostaglandine F2 $\alpha$ analogue	Multidrug-resistant tuberculosis for pediatrics / Oral  Dry eyes / Eye drops MD (multi dose)  Patient preoperative preparation / Topical  Peripheral parenteral nutrition solution/ Injection  COPD / Oral  Dry AMD / Oral  Glaucoma / Eye Drops  Glaucoma / Eye Drops	US EU JP JP JP US, Asia US US		/ 11		Filed	Аррго

Note: In general, Otsuka discloses compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.

<Events after June 30, 2014> Levetiracetam injection / Epilepsy (partial onset seizures): approved in July in Japan; Levetiracetam injection / Epilepsy (partial onset seizures -monotherapy): filed in July in Japan; Brexpiprazole / Adjunctive therapy for major depressive disorder-schizophrenia: filed in July in the U.S.; Tazobactam-Piperacillin injection/ Febrile neutropenia: filed in July in Japan; Delamanid / Multidrug-resistant tuberculosis: approved in July in Japan

#### Research and Development Activities



Hi-Z Tower, Tokushima Research Institute (Otsuka Pharmaceutical)



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



Tsukuba Research Center (Taiho Pharmaceutical)



Tokushima Research Center (Taiho Pharmaceutical)



- O Pharmaceutical segment
- Nutraceutical segment



Otsuka Shanghai Research Institute



Otsuka Maryland Medicinal Laboratories



#### PHARMACEUTICAL SEGMENT

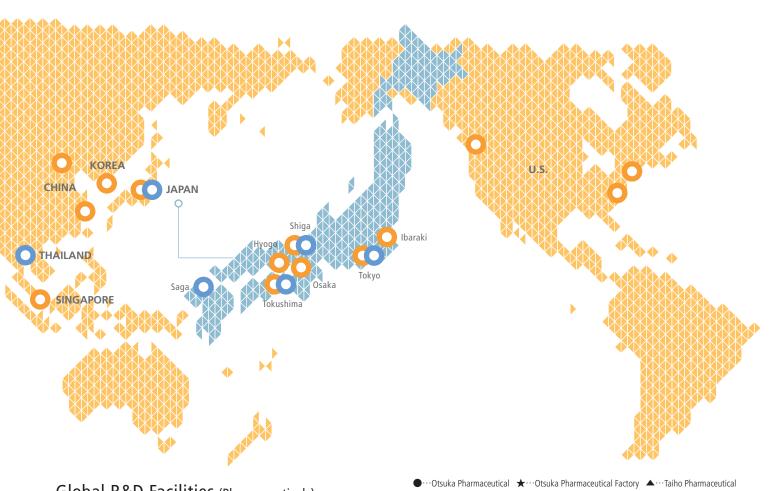
Otsuka-people creating new products for better health worldwide





Fujii Memorial Research Institute (Otsuka Pharmaceutical)

Medical Foods Research Institute (Otsuka Pharmaceutical Factory)



#### Global R&D Facilities (Pharmaceuticals)

	Tokushima		
	First Institute of New Drug Discovery	Formulation Research Institute	★ Technical Center
	<ul> <li>Third Institute of New Drug Discovery</li> </ul>	<ul> <li>Qs' Research Institute</li> </ul>	★ Medical Foods Research Institute
	<ul> <li>Microbiological Research Institute</li> </ul>	<ul> <li>Institute of Biomedical Innovation</li> </ul>	▲ Tokushima Research Center
	Medical Chemistry Research Institute	R&D department of Diagnostic Division	
	Tokushima Research Institute	* Research and Development Center	
JAPAN	Shiga	Hyogo	Ibaraki
	Fujii Memorial Research Institute	Ako Research Institute	Tsukuba Research Center
	Tokyo		
	<ul> <li>R&amp;D department of Diagnostic Division</li> </ul>	▲ Clinical Development Division	
	★ Research and Development Center Cli	nical Development Department	
	Osaka		
	<ul> <li>Division of New Product Evaluation an</li> </ul>	d Development	

U.S.	<ul> <li>Otsuka Maryland Medicinal Laboratories</li> <li>★ US Business Development Division</li> <li>Astex Pharmaceuticals</li> <li>Otsuka Pharmaceutical Development &amp; Commercialization</li> <li>▲ Taiho Oncology</li> </ul>
UK	Astex Pharmaceuticals     Otsuka Europe Development and Commercialisation
GERMANY	Otsuka Novel Products
CHINA	<ul> <li>Otsuka Shanghai Research Institute</li> <li>Otsuka Beijing Research Institute</li> <li>Taiho Pharmaceutical of Beijing</li> </ul>
KOREA	Korea Otsuka Pharmaceutical
SINGAPORE	▲ Taiho Pharma Singapore

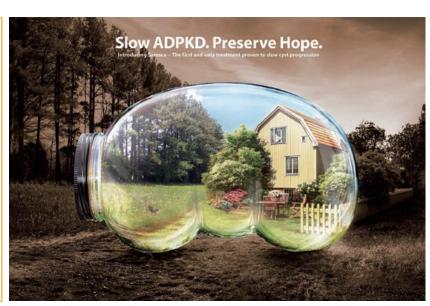
Basic Research Clinical Development

Feature 1

## **Long-term Drug Discovery Initiatives Targeting Rare Diseases**

A New Medical Treatment Category for the Oral Vasopressin V<sub>2</sub>-Receptor Antagonist *Samsca* Japan: First in the World to Approve *Samsca* as a Treatment for ADPKD, a Rare Kidney Disease





# Tackling the Challenge of ADPKD, Which Had No Drug Treatment Until Now

In 1983, Otsuka embarked on the challenging journey of developing a first-in-class diuretic that promotes the excretion of free water only. Development continued for 26 years. Today, the vasopressin V<sub>2</sub>-receptor antagonist *Samsca* (tolvaptan) is available in 20 countries as a diuretic that promotes the excretion of free water only.

The potential of tolvaptan, created through R&D that pursued untraveled paths, goes beyond just one pharmacological application. In September 2003, an American university announced in the international scientific journal *Nature Medicine* that the vasopressin V<sub>2</sub>-receptor antagonist OPC-32160 (mozavaptan) provided by Otsuka Pharmaceutical inhibited in an animal model the proliferation and enlargement of kidney cysts in autosomal dominant polycystic kidney disease (ADPKD\*), a genetic kidney disease with no drug treatment. In response to this announcement, Otsuka management reasoned: "Does this disease have any other treatment method? Are any other companies doing drug development right now? If we don't do it,

no one else will. In that case, we have to do it." From this decision began in 2004 the challenge to develop tolvaptan as the ADPKD treatment, eagerly awaited by patients around the world.

A large international cooperative group clinical trial started in 2007, engaging passionate researchers around the world. As a result, in 2014 Japan became the first country in the world to approve the drug as an ADPKD treatment. At present, an approval application is filed in Europe and a Phase 3 trial is being conducted in the U.S.

\* Autosomal Dominant Polycystic Kidney Disease (ADPKD) is a genetic disease in which countless cysts (fluid-filled sacs) develop in both kidneys, causing the kidneys to become many times larger and resulting in a gradual decline in kidney function. There is a 50% certainty of passing on the disease to a child if either parent has ADPKD. Kidney function continues to decline from ADPKD, and nearly half of patients in Japan will develop end-stage kidney disease by age 70 and require dialysis or kidney transplantation. ADPKD has a high frequency of occurrence among genetic diseases. There are approximately 30,000 diagnosed patients in Japan, 200,000 in Europe, and 120,000 in the U.S. (Source: Nephron 1998, EMA, ADPKD Epidemiology Study Reporting Diagnosed Cases, TOLV-002)



# The Challenge of a Global Clinical Trial Striving to Gather High-quality Evidence

A global Phase-3 clinical trial (TEMPO3:4) involving 1,445 ADPKD patients in 15 countries\* assessed the efficacy and safety of tolvaptan against ADPKD progression and showed that it suppressed the growth in kidney volume. It is suggested that tolvaptan suppresses the growth of kidney cysts by inhibiting the production of cAMP in the cells triggered by vasopressin through the drug's action as a vasopressin V2-receptor antagonist. The trial results were published in November 2012 in the *New England Journal of Medicine*, one of the medical community's most prestigious journals.





#### TOPICS

#### Fruition of Over 30 Years of R&D:

# Marketing Commences After Approval of the Multidrug-resistant Tuberculosis Treatment *Deltyba* in Europe and Japan

Otsuka Pharmaceutical has persevered for more than 30 years with R&D to create a new drug for tuberculosis (TB), a disease that had been previously declared defeated but has unfortunately reappeared. Today, multidrug-resistant tuberculosis (MDR-TB), which is resistant to conventional antibiotic drugs like isoniazid and rifampicin, has become a new problem. Each year about 450,000 people worldwide develop MDR-TB, and nearly 170,000 die of the disease. With a low treatment success rate, MDR-TB has become a global threat.

Deltyba (delamanid), a drug discovered and developed by Otsuka Pharmaceutical, is a treatment for MDR-TB. It has a new mechanism of action that inhibits the production of mycolic acids, which form the cell walls of TB bacteria. The world's largest clinical trial conducted in the TB field, carried out at 17 facilities in nine countries, confirmed its efficacy in clearing TB bacteria. The trial results were published in the New England Journal of Medicine in June 2012.

In April 2014, after world had been waiting nearly half a century for a new TB treatment, *Deltyba* was approved in Europe for use as part of an appropriate combination regimen for MDR-TB in adult patients. *Deltyba* has been launched in Germany and the UK. The drug was also approved for marketing in Japan in July 2014.



Feature 2

#### Taiho Pharmaceutical's Oncology Business Takes Another Major Step





Kitajima Plant, the manufacturing site for Lonsurf



# Japan Leads the World in the Approval and Launch of Lonsurf, an Oral Anti-cancer Drug Discovered In-house

Marketing of Lonsurf, an oral anti-cancer drug discovered in-house by Taiho Pharmaceutical, began in Japan in May 2014.

Lonsurf is an antineoplastic nucleoside analog. In March 2014, Japan became the first country in the world to approve the drug for the treatment of patients with unresectable advanced or recurrent colorectal cancer (only if refractory to standard therapies) based on the results of a randomized, double-blind, placebo-controlled Phase 2 clinical trial conducted in Japan.

Taiho Pharmaceutical is proud to make *Lonsurf* available to physicians in Japan as a new treatment option for patients with metastatic colorectal cancer refractory to standard therapies.



# TAS-102 Demonstrates Statistically Significant Improvement in Overall Survival in Global Phase 3 RECOURSE Trial Study Findings Form Foundation for Populatory Submissions in U.S. and Furance Countries for Populatory Submis

— Study Findings Form Foundation for Regulatory Submissions in U.S. and Europe

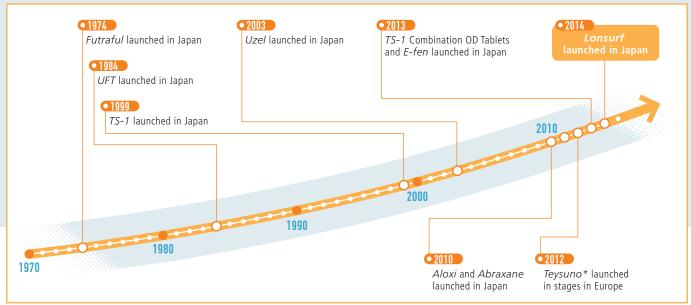
Detailed findings from Taiho Pharmaceutical's global randomized, double-blind, placebo-controlled Phase 3 comparison trial evaluating the efficacy and safety of orally administered TAS-102\* in patients with refractory metastatic colorectal cancer (mCRC) were presented at the European Society for Medical Oncology (ESMO) 16th World Congress on Gastrointestinal Cancer. TAS-102 achieved statistically significant improvements in overall survival, the primary efficacy endpoint, in patients with refractory mCRC whose disease had progressed after or who were intolerant to standard therapies. TAS-102 demonstrated a safety profile consistent with that observed in earlier clinical trials.

Based on the trial results, Taiho plans to submit an NDA in the U.S. at the end of 2014 and an MAA in Europe in the first guarter of 2015.

\* Investigational new drug number for Lonsurf



#### History of Taiho's Oncology Product Development



\* Brand name of S-1 in Europe

- Over its 50-year history, Taiho Pharmaceutical has made the field of oncology a major foundation of its business. The company has produced a number of Japan's foremost anti-cancer drugs and has established itself as a leading company in Japan.
- Taiho has expanded its product lineup in supportive care, which contributes to improvement of the quality of life of patients undergoing treatment for cancer.
- In the future, Taiho will accelerate the globalization of its oncology business with the aim of benefiting patients worldwide who are eagerly awaiting groundbreaking new drugs.



#### Compounds Expected to Advance to Clinical Stage

As of June 30, 2014

TAS-117	Highly potent and selective allosteric AKT inhibitor which inhibits kinase activity	Preclinical
TAS-119	Selective Aurora A inhibitor	Preclinical
TAS-120	Highly potent and selective irreversible FGFR inhibitor	Preclinical
TAS-121	Mutant-selective EGFR inhibitor	Preclinical

<sup>\*</sup> See Pipeline Information on pages 20–21 for compounds at the clinical development stage.



#### 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.



#### Sales Activities

Sales volume for our *Pocari Sweat* range of products increased during fiscal 2013. In April 2013, the Group launched *Pocari Sweat Ion Water*, a new addition to its *Pocari Sweat* electrolyte drink range in Japan, with activities focusing on sales promotions, including taste testing. In combination with the traditional *Pocari Sweat* product, *Pocari Sweat Ion Water* provides a new choice for customers depending on drinking occasion, for example during exercise or while working in the office, or taste preference.

Overseas, where *Pocari Sweat* is sold in 16 markets worldwide, consumption expanded in Indonesia along with the growing number of middle-income earners. IT-based efficiency improvements to our marketing system in China also resulted in an increase in new customers.

The Otsuka Group continues to develop its soy-related business, based on the concept of "Soylution," which sees soy as a solution to various health and environmental issues faced by consumers today. Our soy bar *SOYJOY*, which is sold in 11 countries, registered strong growth in market share, new customers and sales volume compared with the previous fiscal year. This reflected the launch of new flavor *SOYJOY Peanuts* in Japan in April 2013, which helped attract more customers, mainly men, to the *SOYJOY* brand.

Two new flavors were added to the *SoyCarat* range in October 2013 – *Nori & Natto* and *Olive Oil & Garlic*. The brand visibility and popularity of *SoyCarat*, a healthy soy snack, has improved, partly as a result of promoting the product as a healthy snack before meals and bedtime. The Group is also working on dietary education initiatives to encourage a wider understanding among consumers of the nutritional benefits of the Group's soy products, including *SoyCarat*, *SOYJOY* and the soy soda beverage *SOYSH*, which is mainly sold through the Group's online shopping website.

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

Sales volume for the balanced nutrition food *Calorie Mate* rose slightly from the previous fiscal year due to sales promotions focused on the product's qualities as a balanced nutrition food.

Our U.S. subsidiary Pharmavite LLC (Pharmavite) supplies Nature



- \*1:Based on 2013 US News & World Report—Pharmacy Times Survey, Nature Made is the #1 Pharmacist Recommended Brand in Eight Segments—Letter Vitamins, Omega-3/Fish Oil, Coenzyme Q10, Flax Seed Oil, Herbal Supplements, Cholesterol Management-Natural, Garlic (tie) and Diabetic Multivitamins (tie).
- \*2:Pharmavite calculation based in part on data reported by Nielsen through its Scantrack® service for the Dietary Supplements category in dollar and unit sales, for the 52-week period ending 4/12/2014 in U.S. food drug mass channels; and for the 52-week period ending 4/12/2014 in U.S. xAOC channels. ©2014The Nielsen Company
- \*3:Based on INTAGE POS data extrapolation (top five brands) for the period 04/01/2013 to 03/30/2014

Made supplements, which have been selected as the leading pharmacist-recommended brand in eight categories\*1 in the U.S., where they have been the number one retail vitamin and supplement brand for the seven consecutive years since 2007.\*2 The Group reinforced its manufacturing and supply framework for Nature Made supplements with the completion of a new plant in the U.S. state of Alabama in June 2013. In Japan, Nature Made VitaMelts supplements (five versions), which dissolve without water, were launched in November 2013. VitaMelts were launched as part of efforts to strengthen the Nature Made brand, mainly among consumers who are not yet accustomed to taking supplements.

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

In the cosmedics area, where the focus is on the concept of "healthy skin," the Group's two brands—one aimed at men and the other at women—registered very strong growth. In the *UL*•*OS* men's skincare brand, which is marking its fifth anniversary, Skin Lotion and Skin Milk now offer the added efficacy of minimizing fine lines and wrinkles

caused by dryness.  $UL \bullet OS$  is currently the leading brand in the men's skincare category based on sales growth\*<sup>3</sup>. In South Korea, where  $UL \bullet OS$  was launched in March 2012, the brand continued to steadily gain ground. This was illustrated by its selection as the top male cosmetics brand for quality in the country's 2013 consumer choice awards, the second year in a row that the brand has won the award, and by growth in the number of stores that stock the  $UL \bullet OS$  range. In the *InnerSignal* brand aimed at women who seek healthy and beautiful skin, the Group continued to make steady progress in building a loyal base of customers by using the mail-order sales channel to acquire new customers and boost repeat business.

Oronine H Ointment, which is marking its 60th anniversary, registered growth in sales volume due to efforts to promote a tubetype product aimed at younger consumers.

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

#### Main Nutraceutical Products



#### Pocari Sweat

A health drink to quickly replenish water and ions (electrolytes), based on the concept of a beverage to support the body during sweating. With a light sweetness, low-calorie *Pocari Sweat Ion Water* was launched in 2013. It is perfect for everyday refreshment in the office or whenever work or exercise makes you perspire.



#### Calorie Mate

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



#### SoyCarat

A healthy soy snack baked with whole soy flour. This snack makes an enjoyable sound, like beans rattling inside the shell.

One bag contains the equivalent of about 50 soybeans.



#### Oronamin C Drink

A handy and delicious carbonated nutritional drink containing amino acids, vitamin C, and other vitamins.



#### SOYJOY

A new type of nutrition bar made using only soybean dough (wheat-free) and various other ingredients. It was the first product to be released under the "Soylution" concept. New SOYJOY Almond & Chocolate was launched on April 21, 2014.



#### SOYSH

A refreshing and clean-tasting soy soda beverage made from whole soybeans including the solids. It is a great choice for those who might care for the distinctive aftertaste of soy.







#### FIBE-MINI

A dietary fiber beverage that provides a handy source of dietary fiber to support the busy modern lifestyle, while also helping you maintain a healthy body and good looks.



#### Nature Made

No.1 vitamin supplement brand in the U.S. *Nature Made VitaMelts* series, which dissolves without water, was launched in 2013.



Otsuka-people creating new products for better health worldwide

#### Millical

With a history of more than 50 years, *Milical* is the best-selling diet food product sold in pharmacies in France. It was launched in Japan on April 7, 2014. Using the unique *Milical* "3.2.2" one-week diet program, dieters can enjoy both snacks and regular meals. *Milical* offers a new way to diet that is easy to sustain.



#### Second-class OTC drug

#### Oronine H Ointment

An ointment for the treatment of skin ailments and injuries that is formulated with chlorhexidine gluconate, which has excellent antiseptic properties.



#### **EQUELLE**

Developed based on many years of soy research, *EQUELLE* is gaining attention for its potential. Across Japan, dedicated staff are now distributing information on *EQUELLE* with the aim of maintaining and improving the health of women and improving their quality of life.



#### Tiovita Drink

A long-selling product that celebrates its 50th anniversary in 2014. This vitamin health drink contains vitamin B1 and other B-group vitamins to help relieve physical exhaustion, as well as the active ingredient taurine and the digestive aid carnitine chloride.



#### **UL·OS**

A face and body skincare brand targeting middle-aged men based on the cosmedics concept of healthy skin support.



#### **InnerSignal**

A skincare brand for women that employs the active ingredient Energy Signal AMP. This ingredient has received new indication approval for complexion whitening as a quasi-drug.



#### Solmack

A natural herb drink that alleviates symptoms associated with hangover, overeating, and upset stomach. It contains selected natural ingredients with bitter and aromatic properties to improve stomach function.

Photo: Solmack Digestive Drink Plus, designated quasi-drug

#### **Nutraceutical Business** Global Operation (As of April 2014)



Beverage production site



Food and supplement production site Note: Areas shown below include sales areas operated by unconsolidated subsidiaries.







#### **Topics**

# A New Type of *POCARI SWEAT Pocari Sweat Ion Water*: First Launch Outside Japan in Taiwan

It has been more than 30 years since Otsuka Pharmaceutical launched *POCARI SWEAT* as a health beverage to replenish water and electrolytes (ions) lost through perspiration, based on the concept of a beverage designed for situations where people perspire. On April 8, 2013, the company launched *Pocari Sweat Ion Water* as a water and electrolyte supplement drink that better fits people's daily

lives today, since tastes and lifestyles have changed. *Pocari Sweat Ion Water* is a new type of *POCARI SWEAT* that offers light sweetness and a clean aftertaste with reduced calories and the same functionality as the original.

As a global product originating in Japan, *POCARI SWEAT* is now sold in 17 countries and regions worldwide. *Pocari Sweat Ion Water* was released for the first time outside Japan in Taiwan on April 1, 2014. Otsuka Pharmaceutical started selling *POCARI SWEAT* in Taiwan in 1982. In 1996, it established King Car Otsuka Co., Ltd., as a joint venture with major Taiwanese soft drink conglomerate King Car Group and began local production.

Going forward, the company will continue pursuing the creation of new markets by fostering awareness of water and electrolyte replenishment through *POCARI SWEAT* and *Pocari Sweat Ion Water* in diverse situations, including during exercise with heavy perspiration and in everyday life, such as while at the office, where moisture is lost from the body, according to the culture and situation of each area.



# A Snack for Busy People New Product Released: SOYJOY Almond & Chocolate

On April 21, 2014, Otsuka Pharmaceutical launched *SOYJOY Almond & Chocolate*, which combines crunchy roasted almonds and fragrant chocolate with soy, finished with a light sweetness. This is a new item in the lineup of *SOYJOY* bars which provide a convenient and delicious way to enjoy whole soy nutrition.

It is essential for busy people to take care of their own health, especially when they are working hard. Otsuka recommends *SOYJOY* as a snack for busy people to deal with hunger and maintain their health. It can be eaten easily in the office without attracting attention, and is a low-glycemic index food which is less likely to cause weight gain since the carbohydrates are absorbed slowly.

Otsuka Pharmaceutical develops products that provide delicious ways to benefit from the nutrition of whole soy, based on the concept of "Soylution"—that soy can provide solutions to human health and environmental issues—and proposes these new forms of soy to the world.

#### Feature 3

## An Equol-containing Food Derived from Soybeans, the Result of a Total Commitment to Research



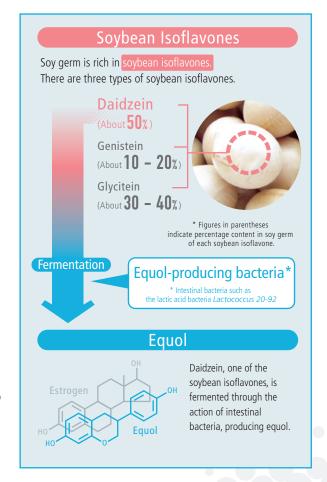
Promoting women's health and extending their healthy lifespan—Otsuka Pharmaceutical has spent many years researching these and other issues faced by women everywhere. After age forty, women reach the menopausal transition, when they undergo a range of physical and emotional changes due to a rapid decrease in hormone (estrogen) levels. Otsuka Pharmaceutical led the world in focusing on the potential of equol, which came out of its soy research. The company conducted thorough collaboration with its Pharmaceutical Business Division and its development labs in the United States to develop the equol-containing food *EQUELLE*, which it released in April 2014.



### Soy-derived Equol

In today's Japan, which has high longevity, people are paying attention to extending their healthy lifespan, the period of time when a high quality of life is maintained and their days are spent in good health. Due to a rapid decrease in hormone levels after age forty, women in particular undergo a range of physical and emotional changes. Women who care for their health at this stage of life can positively affect their subsequent quality of life and extend their healthy lifespan. Otsuka Pharmaceutical focused on equol, a component derived from soybeans. Equol is a metabolite produced from daidzein, a soybean isoflavone, through the action of intestinal bacteria. It is produced within the intestine from soybeans and acts like a weak female hormone (estrogen). The consumption of soybeans or soy isoflavones can therefore be expected to contribute to the maintenance and betterment of women's health.

However, it is said that equol is produced in the body by only around 50% of people who actually eat soybeans, such as the Japanese and Chinese, and by only about 30% of American and European women. The intestinal bacteria of women who are able to produce equol may fluctuate on a daily basis depending upon their health status and stress levels, so that equol production may vary, or even cease suddenly. Otsuka Pharmaceutical believes it is important for the maintenance and improvement of women's health that all women, both those who can and cannot produce equol, consume equol on a daily basis.





## Collaboration with the Pharmaceutical Business Division and Labs in the U.S.: Otsuka Pharmaceutical's unique, "never-give-up" approach to R&D

Otsuka Pharmaceutical began research into equol in 1996 at the Saga Nutraceuticals Research Institute. It had already been reported that intestinal bacteria produce equol, but the identity of the bacteria was still a mystery. The company started by looking for bacteria that could be used as a food. That journey was fraught with difficulties, but the researchers' efforts eventually led to the discovery of the lactic acid bacteria *Lactococcus* 20-92, which produces equol, and it was successfully isolated in 2002. The researchers' determined enthusiasm made possible a big step toward the commercialization of an equol-containing food.

#### **Segment Overview**

Under the motto of "delicious, safe, reassuring, and healthy,"
Otsuka Foods has been offering new culinary lifestyles and creating
new markets with its products.

In the food products business, *Bon Curry* was launched in 1968, becoming the world's first commercially available pouch-packed food product. Then came *Mannan Hikari*, *My Size*, and other products that were ahead of their times. In 2013, the long-selling *Bon Curry* underwent further evolution when *Bon Curry Gold* was launched as a pouch-packed product that can be microwaved in its box. Subsequently, the entire *My Size* series was re-introduced in a format for microwave cooking.

In the beverages business, Otsuka Foods offers a lineup of products that match consumers' various lifestyles and 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.









MATCH



Ridge Wine



Sinvino Java Tea Straight



Bon Curry Neo

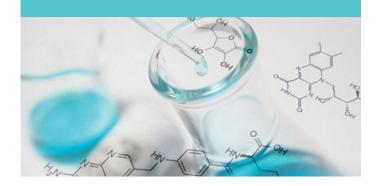


Mannan Hikari

#### OTHER SEGMENT

#### **Segment Overview**

multiple businesses such as chemicals, transportation, warehousing, and electronic equipment.



#### Chemicals

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

#### TOPIC 1

#### Microwaveable Products

In February 2013, *Bon Curry Gold* was launched as a further evolution of *Bon Curry*. Unlike traditional retort packs that are heated in boiling water, all you have to do is open the box top and put the entire package in the microwave. Since no boiling water is required, anyone can use this safe, simple and convenient way to enjoy a delicious hot meal.

Under the concept of "a meal that's just the right size," the *My Size* series was also updated for microwave cooking. Now all of Otsuka's major pouch-packed food products are microwaveable.

Otsuka Foods aims to further grow this market. As a pioneer of retort pouch-pack food products, the company continues to improve their value, and will carry on offering these next-generation foods.





#### TOPIC 2

## Pink Grapefruit Flavor Added to the **MATCH** Line of Carbonated Vitamin Drinks

On March 17, 2014, Otsuka Foods released *MATCH Pink* across Japan as a new line in the *MATCH* series of carbonated vitamin beverages.

While maintaining the MATCH concept of a carbonated vitamin beverage with refreshing flavor and perfect sweetness, MATCH Pink offers a touch of delicious pink grapefruit flavor to accentuate the original MATCH taste. With just the right level of sweetness, it leaves a refreshing aftertaste.

MATCH Pink has almost three times as much Vitamin C content —1,000 milligrams—as the original. The new product targets women in their teens and early twenties who are becoming aware of health and beauty habits. The aim is to develop new fans of the product.

Otsuka-people creating new products for better health worldwide

#### Transportation and Warehousing

By distributing products to market for the Otsuka Group as well as for other firms, Otsuka Warehouse has experienced significant growth along with a rapid increase in the amount of inventory it handles. In response to this, the company has adopted the concept of a data-based ID Warehouse, as it moves away from management based mostly on experience and intuition.

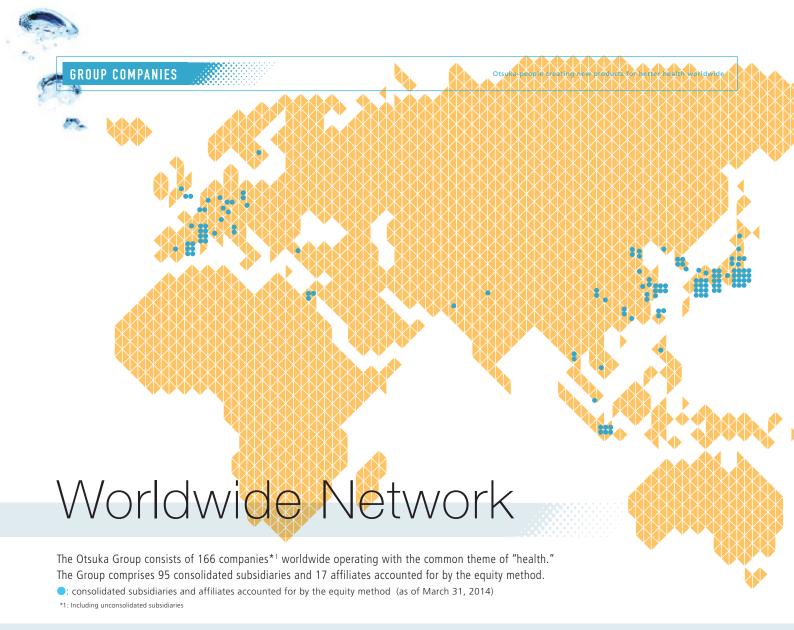
In 2013, iPads were introduced at its logistics centers. Each device can manage the entire process from product arrival to inventory management and shipping.

In the future, the devices will be integrated into the system to create new logistics mechanisms and optimize distribution for the Otsuka Group and other companies.



#### **Electronic Equipment**

Otsuka Electronics develops, manufactures, and markets optical evaluation/inspection equipment for LED light-source luminance and liquid crystal display 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.



[ 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.
- Otsuka-MGC Chemical Company, Inc.
- Otsuka Furniture Manufacturing and Sales Co., Ltd.
- Otsuka Foods Co., Ltd.
- Otsuka Chilled Foods Co., Ltd.
- Otsuka Techno Corporation
- Otsuka Electronics Co., Ltd.
- Otsuka Packaging Industries Co., Ltd.
- Okayama Taiho Pharmaceutical Co., Ltd.
- KiSCO Co., Ltd.
- J.O. Pharma Co., Ltd.
- JIMRO Co., Ltd.
- ILS, Inc. (Former name: Ito Life Sciences Inc.)
- Otsuka Ohmi Ceramics Co., Ltd.
- Otsuka Turftech Co., Ltd.
- Otsuka Naruto Development, Inc.
- Otsuka Ridge Co., Ltd.
- Dairin Integrated Transportation Co., Ltd.
- Nippon Pharmaceutical Chemicals Co., Ltd.
- HAIESU Service Co., Ltd.
- Earth Chemical Co., Ltd.

- Earth Environmental Service Co., Ltd.
- Nichiban Co., Ltd.
- NEOS Corporation
- Agri Best Co., Ltd.
- Chuo Electronic Measurement Co., Ltd.
- Naruto Cruise Service Co., Ltd.
- Heartful Kawauchi Co., Ltd.
- Earth Biochemical Co., Ltd.
- Awa Union Transportation Co., Ltd.
- Kitasato-Otsuka Biomedical Assay Laboratories Co., Ltd.
- Tokushima Vortis Co., Ltd.
- Tokushima Air Terminal Building Co., Ltd.
- Naruto Salt Mfg. Co., Ltd.
- Bean Stalk Snow Co., Ltd.
- Big Bell Co., Ltd.
- Marukita Furniture Center (tentative)
- Yoshino Farm (tentative)
- Ribomic, Inc.
- NitteleOplus Co., Ltd

#### [ Americas ]

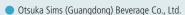
- Otsuka America, Inc.
- American Peptide Company, Inc.
- Astex Pharmaceuticals, Inc.
- Cambridge Isotope Laboratories, Inc.
- CIL Isotope Separations, LLC
- Crystal Geyser Water Company
- Membrane Receptor Technologies, LLC
- Otsuka America Foods, Inc.

- Otsuka America Pharmaceutical, Inc.
- Otsuka Global Insurance, Inc.
- Otsuka Maryland Medicinal Laboratories, Inc.
- Otsuka Pharmaceutical Development & Commercialization, Inc.
- Pharmavite LLC
- Pharmavite Direct LLC
- Ridge Vineyards, Inc.
- Soma Beverage Company, LLC
- Otsuka Canada Pharmaceutical, Inc.
- 2768691 Canada, Inc.
- Otsuka Chemical do Brasil Ltda.
- CG Roxane LLC
- Crystal Geyser Brand Holdings, LLC
- Oncomembrane, Inc.
- Otsuka Chemical America, Inc.
- Taiho Pharma U.S.A., Inc.\*2
- Galenea Corp.
- Graceland Fruit, Inc.
- \*2: Company name changed to Taiho Oncology, Inc. in April 2014.

#### [ Asia, others ]

- Korea OIAA Co., Ltd.
- Korea Otsuka Pharmaceutical Co., Ltd.
- KOC Co., Ltd.
- Otsuka Electronics Korea Co., Ltd.
- Taiwan Otsuka Pharmaceutical Co., Ltd.
- Sichuan Otsuka Pharmaceutical Co., Ltd.
- Otsuka (China) Investment Co., Ltd.
- Otsuka Beijing Research Institute
- Otsuka Pharmaceutical (H.K.) Ltd.





- Pharmavite (Shanghai) Business Information Consultancy Co., Ltd.
- Shanghai Otsuka Foods Co., Ltd.
- Suzhou Otsuka Pharmaceutical Co., Ltd.
- Tianjin Otsuka Beverage Co., Ltd.
- Zhangjiagang Otsuka Chemical Co., Ltd.
- Zhejiang Otsuka Pharmaceutical Co., Ltd.
- 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
- Claris Otsuka Limited
- Otsuka Chemical (India) Private Limited
- Egypt Otsuka Pharmaceutical Co., S.A.E.
- Otsuka (Philippines) Pharmaceutical, Inc.
- Giant Harvest, Ltd.
- Otsuka Pakistan Ltd.
- Dong-A Otsuka Co., Ltd.
- King Car Otsuka Co., Ltd.
- China Otsuka Pharmaceutical Co., Ltd.
- Guangdong Otsuka Pharmaceutical Co., Ltd.
- Shanghai MicroPort Medical (Group) Co., Ltd.
- VV Food & Beverage Co., Ltd.
- Thai Otsuka Pharmaceutical Co., Ltd.
- Diatranz Otsuka Limited
- MicroPort Scientific Corporation
- Otsuka Tech Electronics Co., Ltd.

Hangzhou Linan Kangle Pharmaceutical Co., Ltd.

48

133

- Changzhou Otsuka Econ Techno Co., Ltd.
- Dalian Otsuka Furniture Co., Ltd.
- Leshan Otsuka Techno Co., Ltd.
- MOC Chemicals Trading (Shanghai) Co., Ltd.
- Nanjing Otsuka Techbond Techno Co., Ltd.
- NOBLE SKILL LIMITED

119

- Otsuka (Shanghai) Foods Safety Research & Development Co., Ltd.
- Otsuka Electronics (Suzhou) Co., Ltd.
- Otsuka Electronics Shanghai Co., Ltd.
- Otsuka Material Science & Technology (Shanghai) Co., Ltd.
- Otsuka Shanghai Research Institute
- Otsuka South China Precision Instruments (Shenzhen) Co., Ltd.
- Taiho Pharmaceutical of Beijing Co., Ltd.
- Taiho Pharma Singapore Pte. Ltd.
- Otsuka Saha Asia Research Co., Ltd.
- Otsuka Import Export, LLC
- Otsuka Trading Africa Co., S.A.E.
- Otsuka Thang Nutrition Co., Ltd.Xiamen United Medical Instruments Co., Ltd.
- Otsuka OPV Joint Stock Company
- Achieva Medical Limited

#### [ Europe ]

- Astex Therapeutics, Ltd.
- Otsuka Pharmaceutical Europe Ltd.
- Otsuka Pharmaceuticals (U.K.) Ltd.
- Nardobel SAS
- Euriso-Top SAS

- Laboratoire Diététique et Santé SAS
- Nutrition & Nature SAS
- Nutrition & Santé SAS

26

18

- Otsuka Pharmaceutical France SAS
- Advanced Biochemical Compounds GmbH
- Cambridge Isotope Laboratories (Europe) GmbH

Approx. 18,000

Approx. 26,000

- Euriso-Top GmbH
- Otsuka Frankfurt Research Institute GmbH
- Otsuka Pharma GmbH
- Hebron S.A.
- Nutrition & Santé Iberia SL
- Otsuka Pharmaceutical, S.A.
- Trocellen Iberica S.A.
- Nutrition & Santé Italia SpA
- Nutrition & Santé Benelux S.A.
- Nutrinat AG
- Otsuka Pharma Scandinavia AB
- Interpharma Praha, a.s.
- ALMA S.A.
- Otsuka Europe Development & Commercialisation, Ltd.
- Taiho Pharma Europe, Limited
- Kisco International SAS
- Otsuka Novel Products GmbH
- Otsuka Pharmaceutical Italy S.r.l.
- Otsuka S.A.
- Otsuka Pharmaceutical (Switzerland) GmbH
- Abdi Ibrahim Otsuka Ilac San. Ve Tic. A.S. / Abdi Ibrahim Otsuka Pharmaceutical Company
- Era Endoscopy S.r.l.



## **NORTH AMERICA**

Operations in North America account for nearly 40% of the Otsuka Group's consolidated sales.

The Pharmaceutical Business contributed to growth by delivering a double-digit increase on a US-dollar basis in sales of the antipsychotic *ABILIFY* over the previous year. In addition, Astex Pharmaceuticals, Inc., joined the Group in October 2013. *Nature Made* supplements manufactured and sold by Pharmavite LLC are driving the Nutraceutical Business.

#### Main Operating Companies





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

Founded in 1989, Otsuka America Pharmaceutical performs marketing and sales of pharmaceuticals and medical devices in the U.S.

The company currently sells products such as the antipsychotic drugs ABILIFY and Abilify Maintena, the aquaretic SAMSCA, the hematopoietic stem-cell pre-transplant regimen Busulfex, the BreathTek kit for diagnosing Helicobacter pylori infection, and the antiplatelet agent Pletal.



## Astex Pharmaceuticals Inc. (Dublin, California)

Established in 1999, Astex Pharmaceuticals is known as a leading company in fragment-based drug discovery. It has a drug discovery center in Cambridge, UK, and a clinical development department in California, USA.

Leveraging its proprietary fragment-based drug discovery technology, the company has advanced eight new compounds to the clinical R&D stage in the past eight years.

In October 2013, the company became a subsidiary of Otsuka Pharmaceutical.





#### Pharmavite LLC (Northridge, California)

Pharmavite manufactures and sells *Nature Made* supplements and the *SOYJOY* soy bar.

Nature Made has been recognized as the No. 1\* over-the-counter supplement in the U.S. for seven consecutive years.

In June 2013, the company newly established a supplement manufacturing plant in Opelika, Alabama, as its second production facility after its Californian base.

\*: Pharmavite calculation based in part on data reported by Nielsen through its ScantrackR service for the Dietary Supplements category in dollar and unit sales, for the 52-week period ending 4/12/2014 in U.S. food drug mass channels; and for the 52-week period ending 4/12/2014 in US xAOC channels. ©2014 The Nielsen Company

## 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 system, oncology, ophthalmology and infectious diseases as a global development center for the pharmaceutical products of Otsuka Pharmaceutical.



## Taiho Oncology, Inc. (Princeton, New Jersey)

(Unconsolidated subsidiary)

Taiho Oncology was established in 2002 as a global development base for the anticancer drugs discovered by Taiho Pharmaceutical.

The team of professionals in New Jersey

works closely with Taiho Pharmaceutical's employees in Japan and cooperates with medical professionals and organizations in the U.S. and Europe to advance the development of new drugs that can contribute to cancer treatment globally.



## **EUROPE**

In our pharmaceutical business in Europe, the antipsychotic *ABILIFY*, the antiplatelet *Pletaal/Pletal*, and the aquaretic *SAMSCA* grew steadily.

In November 2013, the aripiprazole injection (depot formulation) *Abilify Maintena* received marketing approval from the European Commission for the maintenance treatment of schizophrenia and was launched sequentially in European countries.

Nutrition & Santé SAS, which has been a consolidated subsidiary since 2009, contributed to expansion of the Nutraceutical Business.

#### Main Operating Companies

#### Otsuka Pharmaceutical Europe Ltd.

(Wexham, United Kingdom)

In October 2013, Otsuka Europe opened a new office to bring the research & development and commercial operations teams together for optimal collaboration.

Otsuka Pharmaceutical Europe Ltd. (OPEL) is the central office for European marketing and sales of pharmaceuticals and medical devices, with offices in the U.K., France, Germany, Italy, Sweden and Spain.

Otsuka Europe's products are: SAMSCA, ABILIFY, Abilify Maintena, Deltyba, Pletal, Adacolumn, 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.



Otsuka-people creating new products for better health worldwide

## **ASIA AND MIDDLE EAST**

The pharmaceutical segment in Asia and the Middle East was built on the foundation of the intravenous solution business that the Group began cultivating in the 1970s.

In July 2013, the joint venture Claris Otsuka was established in India. By providing high-quality basic solutions and clinical nutrition products, the Group aims to contribute to the advancement of medical care in India.

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

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

Manufactures and sells Pocari Sweat and sells SOYIOY 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.



#### 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.



#### Otsuka Shanghai Research Institute (Shanghai, China)

(Unconsolidated 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.



### Shanghai Otsuka Foods Co., Ltd.

(Shanghai, China)

Shanghai Otsuka Foods was established in 2003 to disseminate and establish curry culture in China. The company manufactures and markets products such as curry



in retort pouches, curry paste, and curry powder and is striving to develop a broad-reaching market by introducing products.

Shanghai Otsuka Foods cooperates with the adjoining Otsuka (Shanghai) Food Safety Research & Development Co., Ltd., to provide safe, reliable, and high-quality products.

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

Manufactures and sells the pharmaceutical intermediate GCLE as a raw material for cephalosporin antibiotics, which are gaining a growing share of the Indian market.



#### Claris Otsuka Ltd. (Ahmedabad, India)

On July 31, 2013, Otsuka Pharmaceutical Factory, Inc., Mitsui & Co., Ltd., and Claris Lifesciences Ltd., a major manufacturer and marketer of intravenous solutions and pharmaceuticals in India, jointly established Claris Otsuka, a new company in the intravenous solutions business.

The Indian market for intravenous products is expected to benefit from increasing demand driven by economic growth and the improvement in middle-class incomes, combined with the development of insurance systems and the increase in the number of medical institutions. In the future, India is expected to become one of the world's biggest users of these products.

Otsuka Pharmaceutical Factory has identified India, which is achieving rapid economic development, as a priority country for its expansion outside Japan. By providing high-quality basic solution products, and in the future introducing new valueadded clinical nutrition products to India, the company aspires to contribute to the advancement of medical care in India.







The Otsuka Group engages in the challenge of conducting research and development to deliver 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. The current framework was adopted to ensure the continuous progression of corporate value and preservation of a highly transparent governance structure. This was achieved through the close cooperation of the Board of Directors, which includes several outside directors, with the Audit and Supervisory Board, also including several outside members, which enables effective utilization of the function of the Audit and Supervisory Board and strengthens the management oversight function.

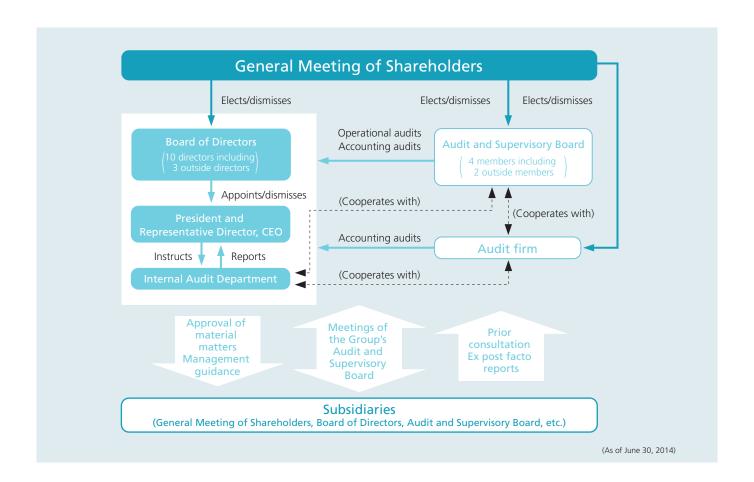
#### Corporate Organization

As a company with a board of corporate auditors, Otsuka Holdings has established a Board of Directors and an Audit and Supervisory Board, and engages an audit firm. The Company pursues sound business management by filling more than half the seats on its Audit and Supervisory Board with outside appointees and by increasing the Audit and Supervisory Board 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 audit and supervisory members 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 June 30, 2014, there are ten directors. Information related to directors' performance of duties is stored and managed appropriately and reliably and maintained in a format accessible when needed, in accordance with the Company Documents Management Rules.



#### Audit and Supervisory Board Members and the Audit and Supervisory Board

Otsuka Holdings has adopted a statutory auditor system. Each audit and supervisory board member attends and expresses opinions at 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 Audit and Supervisory Board at the core of this process.

Systems have been put in place for audit and supervisory members 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 audit and supervisory board members are conducted effectively. An Audit and Supervisory Board Members' Office has been established to assist the duties of audit and supervisory board members. It conducts the work of convening meetings of the audit and supervisory board members and assisting in the duties of audit and supervisory board members independent of the chain of command of board directors.

Furthermore, audit and supervisory board members 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. An audit and supervisory member, Hiroshi Sugawara, holds qualifications as a certified public accountant and has considerable expertise in financial affairs and accounting.

#### Outside Directors and Outside Audit and Supervisory Board Members

The role of the outside directors is to enhance the governance function of the Board of Directors. This involves overseeing business execution and ensuring appropriate decision making through the provision of effective advice from a neutral and objective viewpoint, based on broad insight and a wealth of experience. When necessary, the outside directors also ascertain conditions in the Internal Control Department, while strengthening and enhancing the management oversight function through the various activities of the Board of Directors.

The outside audit and supervisory board members conduct audit work from a neutral and objective viewpoint, based on a wealth of experience relating to corporate management and deep insight into finance, accounting and management. Their role is to strengthen the oversight function while improving management transparency through appropriate advice to the Board of Directors. Outside audit and supervisory board members 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.

In addition to maintaining their independence, Otsuka's outside directors and outside audit and supervisory board members have deep insight and a wealth of experience in corporate management.

Until the end of March 2013, outside director Yasuyuki Hirotomi was Vice President and Representative Director of Resona Bank, Ltd. He currently serves as President of The Resona Foundation for Asia and Oceania, Outside Director of Elecom Co., Ltd., and Vice President, Director, and Executive Officer of Kyosei Steel Ltd. Resona Bank is one of Otsuka's principal lenders. The Otsuka Group has no transactions with The Resona Foundation for Asia and Oceania, Elecom, or Kyosei Steel. Outside director Juichi Kawaguchi has no prior relationship with Otsuka Holdings, and has no personal or capital interests in the Company, nor any business relationships with it. Until the end of April 2011, outside director Tadaaki Kounose was President and Representative Director of Megmilk Snow Brand Co., Ltd., and a member of the Administrative Council of the University of Miyazaki. Otsuka Holdings and Megmilk Snow Brand have transactions through each other's subsidiaries, but the monetary amount is insignificant. The Company has no transactions with University of Miyazaki.

As of June 30, 2014, outside audit and supervisory board members

Norikazu Yahagi and Hiroshi Sugawara held 15,000 and 4,000 shares,
respectively, of common stock in Otsuka Holdings. Norikazu Yahagi is also an
outside audit and supervisory board member of T.D.I. Co., Ltd. Otsuka
Holdings has no business relationship with this company. Hiroshi Sugawara
is also an outside audit and supervisory board member for Otsuka
Pharmaceutical Co., Ltd., a vice president of Will Capital Management
Co., Ltd., and an outside director of Nippon Parking Development Co., Ltd.
Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings. The Company has
no business relationship with Will Capital Management or Nippon Parking
Development. Otsuka Holdings has designated outside directors Juichi
Kawaguchi and Tadaaki Kounose as well as outside audit and supervisory
board members Norikazu Yahagi and Hiroshi Sugawara as independent
officers, as regulated by the Tokyo Stock Exchange, and notified the Tokyo
Stock Exchange thereof.

The following criteria are used for appointing outside directors and outside audit and supervisory board members.

Outside directors and outside audit and supervisory board members must be capable persons with abundant knowledge and experience in various fields. They must be able to demonstrate adequate oversight of the directors by performing fair and objective management supervision and monitoring, or auditing, 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 for independence pertaining to past duties and career history, other than having not engaged in the administration of business matters in a Group company. 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 outside directors and outside audit and supervisory board members.



- \* Criteria for Judgment of Independence specified by the Tokyo Stock Exchange 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
- b. A person who has the company concerned as his/her main business partner or is an operating officer, etc, or 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 outside audit and supervisory board member is to be designated an independent officer: a director who is not an operating officer; or a person who was a director but 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 (four auditors as of June 30, 2014) which reports directly to 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 submits audit reports to the president, directors, and audit and supervisory board members. 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 audit and supervisory members 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 the auditing firm Deloitte Touche Tohmatsu LLC to audit the Company's accounts from a fair

and impartial stance. The certified public accountants who audited the Company's accounts were Mitsuru Hirano, Yukitaka Maruchi, and Koichi Niki. They were assisted by nine other 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. An Audit and Supervisory Board has been established, enabling several of its members to audit the directors' performance of duties and thereby increase their effectiveness. Audit and supervisory board members 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 Audit and Supervisory Board, the audit and supervisory board members audit the execution of operations by the directors. Also, as a general rule, a meeting of the Group's audit and supervisory members is convened twice a year.

Audit and supervisory board members 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.

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.

### Otsuka Museum of Art: Collection of Ceramic Board Masterpieces Unparalleled in the World

The Otsuka Museum of Art was established in 1998 to commemorate the 75th anniversary of the founding of the Otsuka Group. It was located in Tokushima Prefecture out of the desire to give back to the people of this region. The museum features more than 1,000 replicas of masterpieces of Western art, from ancient murals to modern paintings. The replicas have been produced as ceramic boards and are faithful reproductions of the originals, allowing visitors to experience artworks housed in the museums of 25 different countries without leaving Japan.

The museum has been recognized for its efforts to convey art history through the use of creative exhibits. This includes displaying ceramic replicas of conceptualized restorations of a set of six high altar panels by El Greco. It is a rare opportunity to appreciate the altarpieces in the same location, as the originals were later dispersed in the Napoleonic wars. The museum also displays the Last Supper by Leonardo da Vinci, in versions before and after it was restored. The museum has drawn a great deal of attention for creating a long-lasting record of these great cultural assets, as the ceramic boards will maintain their colors and appearance indefinitely, while the original artworks inevitably fade and deteriorate.

As part its community-focused efforts, the museum holds workshops and events that enable local people to enjoy art in their daily lives. By giving children exposure to masterpieces at an early age, the museum hopes to create opportunities to foster interest in fine art, culture, and the wider world. The aim is to create a museum that can provide a deeper and more enjoyable art experience.

The Sistine Hall is the museum's full-size interior reproduction of the Vatican's Sistine Chapel. Every year since 2009, this hall has been the venue for an original Kabuki production. Based on the concept of Japanese-Western collaboration the Kabuki drama is adapted to incorporate elements of European performance art. The combination of Michelangelo's masterpieces and traditional Japanese kabuki also becomes a topic of interest every time it is held.

The Otsuka Museum of Art will continue to contribute to the local community by promoting the popularization of art and culture. This effort is based on a spirit of creativity, which is one of the philosophies of the Otsuka Group.





Inside the Otsuka Museum of Art

## Healthcare Support Activities: Otsuka Welfare Clinic

In 2003, the Otsuka Group established the Otsuka Welfare Clinic in Peshawar, Pakistan, to provide medical treatment to Afghan refugees. Treatment is provided free of charge to those that need it. In December 2013, on the 10th anniversary of the clinic's establishment, a local commemoration ceremony was held. Since the terrorist attacks on September 11, 2001 in the United States, and the subsequent



operation in Afghanistan, 1.8 million Afghan refugees have poured into Pakistan. However, many of them were unable to get satisfactory medical treatment. With a strong desire to contribute to the health of local people as a healthcare company in Asian and Arab countries, the Otsuka Group decided to provide free medical treatment to refugees who need it. The Otsuka Welfare Clinic was jointly set up by Otsuka Pharmaceutical and the 23 Group companies that operate in Asian and Arab countries. With the ongoing fighting in the region, approximately 150 people visit the clinic each day, and the total number has risen to more than 700,000 people over 10 years.

During heavy floods in 2010, the clinic mobilized to set up a temporary relief center in a nearby area that was severely impacted. By providing not just treatment but also medicines free of charge, the activities of the Otsuka Welfare Clinic have won high regard. In 2011, Otsuka received a letter of appreciation from the Ambassador of Japan to Pakistan, and in 2014, Otsuka accepted a Foreign Minister's Commendation in Japan for the clinic's many years of service. The Otsuka Group will continue to provide support activities rooted in local communities in order to contribute to the health of people around the world.

### Eco-Friendly Plants: Living in Harmony with Nature

Otsuka Pharmaceutical's Tokushima Itano Factory was designed to be an eco-friendly and community-friendly plant, with greenery covering some 70% of the grounds. The site features a biotope that offers a natural environment for diverse wildlife and also encompasses a section of untouched forest with evergreen oak trees and other vegetation that is home to different species of birds depending on the time of year.

The biotope pond is fed with purified wastewater from the plant's cooling system. Once a natural aquatic environment was created in which a wide variety of organisms could live, the factory and Tokushima Prefecture stocked the pond with golden venus chub, an endangered freshwater species of cyprinid fish. After the fish grow and breed in the pond, they are re-introduced to native habitats. In recognition of these nature conservation activities, in 2010, Otsuka Pharmaceutical was chosen as one of the top 100 green companies for biodiversity conservation by the Organization for Landscape and Urban Green Infrastructure. Otsuka Pharmaceutical also received a fiscal 2011 Minister of the Environment Award for efforts to establish a sound material-cycle society.

With a park-like setting that combines nature and human activities in a lush hilly area, the Tokushima Wajiki Factory of Otsuka Pharmaceutical carries out eco-friendly production. It also actively participates in local nature conservation activities, and is involved in the Acorn Project of the Tokushima Prefecture Government South District



Otsuka Pharmaceutical's Tokushima Itano Factory



Taiho Pharmaceutical's Okayama Factory

Administration Bureau. The project raises seedlings of acorn-bearing trees that are native to the region. Once the seedlings are large enough, they are distributed to local communities and also planted on the factory grounds.

Located in a scenic spot overlooking Kugui Bay in the city of Bizen, the Okayama Factory of Taiho Pharmaceutical uses eco-friendly wastewater treatment methods to purify cooling and cleaning water generated from manufacturing. This enables the plant to discharge the treated water into the sea in a condition closer to its natural state. In the biotope on the factory grounds, there is a variety of features such as a babbling brook, a deep pool, and sandbars, creating an environment in which fish and small animals can thrive. They look for food along the water's edge, and the habitat also attracts insects and birds.

The treated wastewater that flows through this biotope is eventually released into the sea and has the same qualities as natural stream water, rich in organic material. This helps to increase the plants and animals in the tidal flats of Kugui Bay. The biotope is thus contributing to regional biodiversity conservation. The Okayama Factory has been recognized for its efforts with the Fiscal 2013 Bizen General Service Bureau Director's Award for Regional Environmental Protection. The factory was also selected as a Fiscal 2014 Okayama Prefecture Eco Tour Learning Facility.

### Otsuka Health Comic Library

Since 1989, the Otsuka Group has been producing the Otsuka Health Comic Library, a collection of comic books that help promote the health of children, the next generation. To date, 24 titles have been published, including a special edition, and every year collections are donated to elementary and special needs schools across Japan. In addition to being read



by children individually, the comics are used as teaching materials for self-directed learning and school health committee activities.

To further increase interest, starting in fiscal 2013, students are being encouraged to submit ideas for health-related topics to be covered in future titles, in the form of illustrations or cartoons. The submissions are then used by the publication's cartoonists to make collaborative comic books. The effort has created good opportunities to think about health, not just for the children whose submissions are utilized, but for their friends, guardians, and teachers. The Otsuka Group intends to continue expanding this initiative that allows children to enjoy learning while reading comics.

#### **Eco-Friendly Products**

The Otsuka Group is working to make eco-friendly products.

In 2007, Otsuka Pharmaceutical adopted Japan's first positive-pressure aseptic filling technology for its 500 ml plastic bottles of *POCARI SWEAT*. This resulted in the lightest weight for this product type in Japan. By making bottle preforms in-house from PET plastic raw material, the bottle cleaning and sterilization process has been eliminated. Thinner bottle labels were then created as part of efforts to further reduce energy and transportation fuel costs. Lighter plastic bottles were also realized for Otsuka Foods' carbonated vitamin drink, *MATCH*. Lightweight glass bottles are being introduced in stages, starting with *Tiovita Drink* from Taiho Pharmaceutical, through the use of technology to strengthen the bottles.

Otsuka Pharmaceutical's French subsidiary, Nutrition & Santé SAS, established its N&S Eco-Design Charter (Eco Charter) to ensure thorough environmental considerations for all its products. The company is undertaking environmentally friendly design throughout the entire process from new product development to procurement of raw materials, manufacturing, packaging material and shape design, and transport.

To help reduce hospital waste from medical supplies, Otsuka Pharmaceutical Factory has developed *ELNEOPA* No. 1 and No. 2 injection solutions as the world's first quad-bag TPN solution kits formulated with glucose, electrolytes, amino acids, vitamins, and trace elements. Compared to conventional TPN solution products that require the mixing of separate formulations, the new products help reduce waste such as



ELNEOPA No. 1 injection solution (quad bag)

containers and needles. In addition, Otsuka Pharmaceutical has developed *Meptin Swinghaler* 10µg (100 puffs), a bronchodilator inhaler product that is more compact and does not contain any propellant, which is harmful to the environment. This has reduced the amount of waste while also being more convenient for patients.

The Otsuka Group will continue striving for environmental protection by developing products with less environmental impact and greater convenience for users.



Otsuka-people creating new products for better health worldwide

### Coexisting with Communities in Indonesia Growth of the Satu Hati (One Heart) Project

With the aim of forging ties with local communities and contributing to the development of Indonesia, P.T. Amerta Indah Otsuka is actively engaged in activities to educate the children who will be the leaders of tomorrow.

Satu Hati (One Heart) began as a charity concert in 2007. The proceeds from the event and donations have been used to support the education of children through activities such as library building and book donation. So far the project has built 25 libraries and donated more than 110,000 books.

In 2013, the theme of "One Heart for Environment" was added, and tree planting was carried out with the aim of regional revitalization and watershed protection in mountains near the company's plant. A soccer field, mosque, and local learning center were set up on the factory grounds, and they are open to



local residents and children. The learning center features a Satu Hati School that is held once a week, where employees take turns providing after-school tutoring in grammar, math, and English.

#### Day Care Centers Support Employees and Local Communities



BeanStalk Kids Center Tokushima



Sukusuku Nursery



BeanStalk
Kids Center Osaka

The Otsuka Group operates on-site day care centers to ensure the future of its creative corporate culture. The centers also contribute to the development of local communities by supporting the diverse lifestyles of employees, and helping them to advance their careers while raising children.

In 2011, BeanStalk Kids Center Tokushima was opened in the prefecture where the Otsuka Group originated, followed by a location in Osaka in 2014. The Sukusuku Nursery was opened at the Tsukuba Research Center in 2013. The premises of these centers and nursery are "nature-like" environments that stimulate the five senses. This helps to foster healthy children with rich emotional development.

At the BeanStalk Kids Center Tokushima, the curriculum incorporates the corporate philosophy of the Otsuka Group, which places importance on creativity. The goal is to provide childcare that fosters the talent, individuality, and creativity of children. With a desire to also support the local economy of Tokushima, materials from the prefecture were used to construct the center, and the work was entrusted to local companies. These efforts have helped strengthen ties with the local community.

Providing support to employees who are trying to balance childcare and work responsibilities helps them to be happier and achieve greater self-actualization. It also improves productivity and leads to a more dynamic company through the maintenance of a workforce with greater diversity. In addition to the creation of day care centers, the Otsuka Group has a full range of programs to support employees including flexible working hours, paid caregiver leave, and telecommuting. The Group will continue to create supportive workplace environments to give employees peace of mind and help them to improve work-life balance.





During the fiscal year ended March 31, 2014, the Japanese economy experienced a mild recovery, with quarterly real GDP growing at a higher rate than the previous year. The corporate operating environment continued to improve gradually assisted by a weaker yen. Outside Japan, growth in emerging economies started to slow down, while economic indicators in Europe and the United Sates improved.

Within this global operating environment, the Otsuka Group reported consolidated net sales of ¥1,452,759 million (19.3% increase from previous year) for the fiscal year ended March 31, 2014, with operating income of ¥198,703 million (17.1% increase) and net income of ¥150,990 million (23.3% increase).

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

#### 1) Pharmaceuticals

Net sales of the pharmaceutical segment were ¥1,035,080 million (21.7% increase from the previous year), consisting mainly of global sales of ABILIFY, Pletaal, TS-1 and SPRYCEL.

#### 2) Nutraceuticals

Net sales of the nutraceutical segment were ¥287,133 million (14.0% increase from the previous year), consisting mainly of sales of Pocari Sweat, Oronamin C, SOYJOY and Nature Made brand supplements as well as functional foods in the European market.

#### 3) Consumer Products

Net sales of the consumer products segment were ¥43,926 million (6.3% decrease from the previous year), consisting mainly of sales of CRYSTAL GEYSER, MATCH and Bon Curry.

#### 4) Others

Net sales of the other segment were ¥130,340 million (16.7% increase from the previous year), consisting of sales of fine chemical and specialty chemical products, as well as revenues from the transportation and warehousing business.

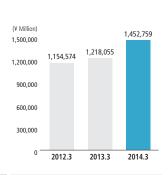
Selling, general and administrative expenses were ¥812,424 million (24.1% increase from the previous year), resulting in an operating income of ¥198,703 million (17.1% increase from the previous year).

Major components of selling, general and administrative expenses included personnel expenses (¥124,042 million), sales promotion expenses (¥192,031 million) and research and development expenses (¥249,010 million).

Other income, totaling ¥11,522 million, included equity in earnings of unconsolidated subsidiaries and affiliated companies (¥3,222 million), foreign exchange gain (¥7,923 million), and loss on impairment of long-lived assets (¥3,399 million).

As a result, net income was ¥150,990 million (23.3% increase from the previous year).

#### **Net Sales**



#### Sales by Business Segment 2014.3 2013.3 2014.3 (¥ Billion) (¥ Billion) Pharmaceuticals — 851 —1,035 Nutraceuticals —— 252 — 287 Consumer Products - 47 — 44 Others -—— 112 — 130 Note: Intersegment sales are included 2013.3

#### Operating Income



#### Financial Position (Graph 6)

#### **Assets**

Total assets as of March 31, 2014 were ¥2,028,400 million, an increase of ¥249,192 million compared to ¥1,779,208 million at the end of the previous fiscal year. The increase was due to a ¥88,198 million increase in current assets and a ¥160,994 million increase in fixed assets.

#### **Current Assets**

Total current assets as of March 31, 2014 were ¥1,168,841 million, an increase of ¥88,198 million compared to ¥1,080,643 million at the end of the previous fiscal year. The increase was due mainly to a ¥25,952 million increase in marketable securities, a ¥29,505 million increase in receivables, and a ¥19,511 million increase in inventories.

#### **Fixed Assets**

Total fixed assets as of March 31, 2014 were ¥859,559 million, an increase of ¥160,994 million compared to ¥698,565 million at the end of the previous fiscal year. The increase was due mainly to a ¥39,218 million increase in property, plant, and equipment as a result of the initial investment in manufacturing facilities at the Kitajima Factory of Taiho Pharmaceutical Co., Ltd., the initial investment in a manufacturing facility at the Alabama Factory of Pharmavite LLC, the newly consolidated manufacturing assets of Claris Otsuka Limited, a ¥32,807 million increase in goodwill, and a ¥85,606 million increase in intangible assets mainly resulting from the first-time consolidation of Claris Otsuka Limited, Astex Pharmaceuticals, Inc. and one other company.

#### Liabilities

#### **Current Liabilities**

Total current liabilities as of March 31, 2014 were ¥437,421 million, an increase of ¥90,949 million compared to ¥346,472 million at the end of the previous fiscal year. The increase was due mainly to a ¥12,247 million increase in short-term borrowings, a ¥54,457 million increase in payables, and a ¥16,654 million increase in other current liabilities.

#### Long-term Liabilities

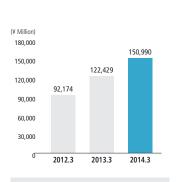
Total long-term liabilities as of March 31, 2014 were \$80,219 million, a decrease of \$27,446 million compared to \$107,665 million at the end of the previous fiscal year. The decrease was due mainly to a \$32,440 million decrease in liability for retirement benefits.

#### Equity

Total equity as of March 31, 2014 was ¥1,510,760 million, an increase of ¥185,689 million compared to ¥1,325,071 million at the end of the previous fiscal year. The increase was due to share buybacks amounting to ¥30,003 million, dividend payments of ¥32,753 million, the recording of ¥150,990 million in net income, and increases of ¥77,837 million in total accumulated other comprehensive income (due mainly to exchange rate impact and the adoption of the revised Accounting Standard for Retirement Benefits) and of ¥11,616 million in minority interests.

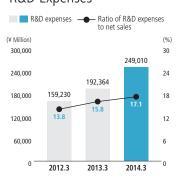
## Graph 4

#### Net Income



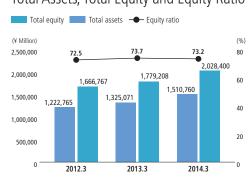
#### Graph 5

#### **R&D** Expenses



#### Graph 6

#### Total Assets, Total Equity and Equity Ratio



#### Cash Flows (Graph 7)

Cash and cash equivalents increased by ¥69,967 million during the fiscal year ended March 31, 2014 to ¥417,538 million. Net cash provided by operating activities was ¥226,462 million, while net cash used in investing activities and financing activities was ¥108,514 million and ¥66,695 million, respectively.

#### Cash Flows from Operating Activities

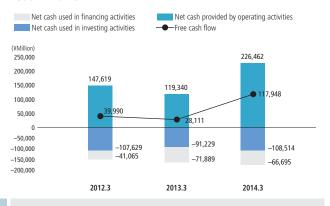
Net cash provided by operating activities was ¥226,462 million in the fiscal year ended March 31, 2014, an increase of ¥107,122 million compared to ¥119,340 million in the previous fiscal year. The main components were ¥210,225 million from income before income taxes and minority interest (an increase of ¥33,286 million compared to ¥176,939 million at the end of the previous fiscal year), ¥49,746 million (¥45,463 million in the previous fiscal year) from depreciation and amortization, ¥12,392 million in trade receivables (an increase of ¥59,632 million from the negative figure of ¥47,240 million at the previous fiscal year end), and income tax payments of ¥66,130 million (¥66,829 million in the previous fiscal year).

#### Cash Flows from Investing Activities

Net cash used in investing activities was ¥108,514 million in the fiscal year ended March 31, 2014, an increase of ¥17,285 million compared to ¥91,229 million in the previous fiscal year. This included ¥95,356 million in purchases of investments in subsidiaries resulting in change in scope of consolidation (an increase of ¥93,817 million compared to ¥1,539 million at the end of the previous fiscal year), ¥48,777 million in purchase of property, plant, and equipment (¥50,541 million in the previous fiscal year), ¥21,166 million in purchases of intangible assets (¥8,914 million in the previous fiscal year), and a ¥59,140 million decrease in short-term investments (a ¥29,091 increase in the previous fiscal year).

#### Graph 7

#### Cash Flows



#### Cash Flows from Financing Activities

Net cash used in financing activities was ¥66,695 million in the fiscal year ended March 31, 2014, a decrease of ¥5,194 million compared to ¥71,889 million in the previous fiscal year. This included ¥32,753 million in payment of dividends (¥29,334 million in the previous fiscal year), and ¥30,003 million in purchase of treasury stock (¥20,002 million in the previous fiscal year).

#### Planned Change in Fiscal Year End

Due to a planned change in the fiscal year end from March 31 to December 31, the fiscal year ending December 31, 2014 will be the nine-month period from April through December for the Group's consolidated financial statements. The nine-month figures from April through December will be used for subsidiaries with a fiscal year end in December.

#### **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, 2014.

#### 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.



#### FINANCIAL REVIEW

Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries
As of March 31, 2014

## (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 are 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 as to 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 approximately 40% 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.

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 United States, the second largest market for our pharmaceutical products, managed care institutions, insurance companies and the government have been promoting the use of generic drugs and there has 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 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, the economic environment, fuel costs and foreign exchange rates. If the cost of 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 of 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 operation 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 render our products or technologies uncompetitive or 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, pay significant damages or pay significant royalties.

In the U.S., the Group filed patent infringement actions against a number of generic drug companies which had sought FDA approval to commercialize generic versions of *ABILIFY*. Judgments in favor of the Group were finalized for these actions in February 2013.

#### (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 environmental issues. In the event of an adverse decision or settlement, our business, financial position 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 portion of such facilities is 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 be no 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 violation could have an adverse affect on our reputation and thus negatively affect our results of operations.

#### (15) We are subject to market risk

In the fiscal year ended March 31, 2014, 56.8% 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 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.

A patent infringement action had 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 had a material adverse effect on our financial condition and results of operations. However, the parties reached a settlement in September 2013 and the case was dismissed, concluding the matter.

## (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 United States, 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, the economic environment, political instability and uncertain business environments. 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 position and results of operations.

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries as of March 31, 2014

		Millions	Thousands of U.S. Dollars (Note 1)	
ASSETS	Notes	2014.3	2013.3	2014.3
Current assets:				
Cash and cash equivalents	9, 18	¥ 417,538	¥ 347,571	\$ 4,056,918
Short-term investments	5, 18	97,279	172,074	945,190
Marketable securities	6, 18	58,456	32,504	567,975
Receivables:	9, 17, 18			
Trade notes		8,121	9,464	78,906
Trade accounts		316,969	306,425	3,079,761
Unconsolidated subsidiaries and affiliated companies		20,007	2,927	194,394
Other		17,946	14,663	174,368
Allowance for doubtful receivables		(602)	(543)	(5,849)
Inventories	7, 9	151,863	132,352	1,475,544
Deferred tax assets	13	54,549	40,837	530,014
Other current assets	9, 17	26,715	22,369	259,571
Total current assets		1,168,841	1,080,643	11,356,792
Property, plant, and equipment:	8, 9			
Land		80,992	76,497	786,941
Buildings and structures		333,292	293,665	3,238,360
Machinery and equipment		345,361	301,419	3,355,626
Furniture and fixtures		83,730	75,073	813,545
Lease assets		15,342	16,858	149,067
Construction in progress		15,880	26,487	154,295
Total property, plant, and equipment		874,597	789,999	8,497,834
Accumulated depreciation		(559,412)	(514,032)	(5,435,407)
Net property, plant, and equipment		315,185	275,967	3,062,427
Investments and other assets:				
Investment securities	6, 18	116,619	118,782	1,133,103
Investments in and advances to unconsolidated subsidiaries and affiliated companies	17, 18	192,822	188,263	1,873,513
Goodwill		70,595	37,788	685,921
Intangible assets	8	121,668	36,062	1,182,161
Deferred tax assets	13	16,939	26,467	164,584
Asset for retirement benefits	10	11,113	_	107,977
Other assets		14,618	15,236	142,034
Total investments and other assets		544,374	422,598	5,289,293
Total		¥2,028,400	¥1,779,208	\$19,708,512

LIABILITIES AND FOLUTY		Millions	Thousands of U.S. Dollars (Note 1)	
LIABILITIES AND EQUITY	Notes	2014.3	2013.3	2014.3
Current liabilities:				
Short-term borrowings	9, 18	¥ 51,293	¥ 39,046	\$ 498,377
Current portion of long-term debt	9, 18	4,551	15,484	44,219
Payables:	18	, , ,	,	,
Trade notes		8,677	8,849	84,308
Trade accounts		122,556	86,985	1,190,789
Construction		7,314	6,284	71,065
Unconsolidated subsidiaries and affiliated companies		4,281	3,444	41,595
Other		80,922	63,731	786,262
Income taxes payable	18	51,064	33,515	496,152
Accrued expenses	10	60,979	58,076	592,489
Provision for loss on business liquidation		00,979		392,469
·	: : :	45.704	1,929	444.054
Other current liabilities	1	45,784	29,129	444,851
Total current liabilities		437,421	346,472	4,250,107
Long-term liabilities:	1			
Long-term habilities: Long-term debt	0.10	20.074	12 222	105.045
3	9,18	20,074	12,332	195,045
Liability for retirement benefits	10	8,131	40,571	79,003
Retirement benefits for directors and audit and supervisory board members		2,588	3,108	25,146
Negative goodwill	20	21,541	24,005	209,298
Long-term unearned revenues	20	5,683	13,389	55,218
Deferred tax liabilities	13	16,658	11,258	161,854
Other long-term liabilities		5,544	3,002	53,868
Total long-term liabilities		80,219	107,665	779,432
Commitments and contingent liabilities	16,19,20			
Communerts and contingent habitities	10,13,20			
Equity:	11,12,24			
Common stock:	11,12,24	81,691	81,691	793,733
Common stock.		61,091	01,091	193,133
Authorized 1 COO 000 000 shares in 2014 and 2012				
Authorized —1,600,000,000 shares in 2014 and 2013 Issued — 557,835,617 shares in 2014 and 2013				
337/333/611 3.14.43 2011 4.14 2013				
Capital curplus		F12 906	F10 422	4 002 442
Capital surplus	: : : :	512,896	510,423	4,983,443
Stock acquisition rights	! ! !	105	105	1,020
Retained earnings		891,615	768,315	8,663,185
Treasury stock, at cost:		(47,929)	(18,392)	(465,692)
16,211,155 shares in 2014 7,593,160 shares in 2013				
Accumulated other comprehensive income:				
Unrealized gain on available-for-sale securities		13,820	8,284	134,279
Deferred loss on derivatives under hedge accounting		(7)	· —	(68)
Foreign currency translation adjustments		12,153	(39,824)	118,082
Defined retirement benefit plans	10	20,331	·	197,542
Total		46,297	(31,540)	449,835
Minority interests		26,085	14,469	253,449
Total equity		1,510,760	1,325,071	14,678,973
Total		¥2,028,400	¥1,779,208	\$19,708,512

#### CONSOLIDATED STATEMENT OF INCOME

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries for the year ended March 31, 2014

	Notes	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	Notes	2014.3	2013.3	2014.3
Net sales	14	¥1,452,759	¥1,218,055	\$14,115,420
Cost of sales		441,632	393,831	4,291,022
Gross profit		1,011,127	824,224	9,824,398
Selling, general, and administrative expenses	15	812,424	654,564	7,893,743
Operating income		198,703	169,660	1,930,655
Other income (expenses):				
Interest and dividend income		2,505	2,876	24,339
Interest expense		(1,237)	(1,211)	(12,019)
Foreign exchange gain, net		7,923	6,204	76,982
Amortization of negative goodwill		2,648	2,464	25,729
Equity in earnings of unconsolidated subsidiaries and affiliated companies		3,222	3,140	31,306
Loss on impairment of long-lived assets	8	(3,399)	(2,571)	(33,026)
Loss on valuation of investment securities and investments in unconsolidated subsidiaries and affiliated companies	6	(211)	(4,408)	(2,050)
Other, net		71	785	690
Other income, net		11,522	7,279	111,951
Income before income taxes and minority interests		210,225	176,939	2,042,606
Income taxes:	13			
Current		81,255	61,990	789,497
Deferred		(23,584)	(8,206)	(229,149)
Total income taxes		57,671	53,784	560,348
Net income before minority interests		152,554	123,155	1,482,258
Minority interests in net income		1,564	726	15,196
Net income		¥ 150,990	¥ 122,429	\$ 1,467,062

		Yε		U.S. Dollar
	Notes	2014.3	2013.3	2014.3
Per share of common stock:	2(t), 23			
Basic net income		¥278.07	¥221.90	\$2.70
Diluted net income		277.52	221.42	2.70
Cash dividends applicable to the year		65.00	58.00	0.63

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 its Consolidated Subsidiaries for the year ended March 31, 2014

	Notes	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
		2014.3	2013.3	2014.3
Net income before minority interests		¥ 152,554	¥ 123,155	\$1,482,258
Other comprehensive income (loss):	21			
Unrealized gain on available-for-sale securities		5,468	7,593	53,129
Deferred loss on derivatives under hedge accounting		(7)	(11)	(68)
Foreign currency translation adjustments		35,698	12,000	346,852
Share of other comprehensive income in affiliated companies		19,158	9,000	186,145
Total other comprehensive income		60,317	28,582	586,058
Comprehensive income	21	¥ 212,871	¥ 151,737	\$2,068,316
Total comprehensive income attributable to:	21			
Owners of the parent		¥ 209,449	¥ 150,034	\$2,035,067
Minority interests		3,422	1,703	33,249

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries for the year ended March 31, 2014

	Thousands							Millio	ns of Yen					
	Outstanding													
	number of shares of common stock	Notes	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	Defined retirement benefit plans		Minority interests	Total equity
Balance, April 1, 2012	557,832		¥81,691	¥510,639	¥1,134	¥ 675,411	¥ (8)	¥ 750	¥11	¥ (59,905)	¥ —	¥1,209,723	¥ 13,042	¥1,222,765
Cash dividends, ¥53 per share						(29,334)						(29,334)		(29,334)
Net income						122,429						122,429		122,429
Disposal of treasury stock	668			(216)			1,618					1,402		1,402
Purchase of treasury stock	(8,258)						(20,002)					(20,002)		(20,002)
Change in scope of consolidation		2(a)				(191)						(191)		(191)
Net change in the year					(1,029)			7,534	(11)	20,081		26,575	1,427	28,002
Balance, March 31, 2013	550,242		¥81,691	¥ 510,423	¥ 105	¥ 768,315	¥ (18,392)	¥ 8,284	¥—	¥ (39,824)	¥ —	¥1,310,602	¥ 14,469	¥1,325,071
Cash dividends, ¥60 per share						(32,753)						(32,753)		(32,753)
Net income						150,990						150,990		150,990
Disposal of treasury stock	167			(114)			466					352		352
Purchase of treasury stock	(8,785)						(30,003)					(30,003)		(30,003)
Change in scope of consolidation		2(a)		2,587		5,063						7,650		7,650
Net change in the year								5,536	(7)	51,977	20,331	77,837	11,616	89,453
Balance, March 31, 2014	541,624		¥81,691	¥512,896	¥ 105	¥891,615	¥ (47,929)	¥ 13,820	¥ (7)	¥ 12,153	¥ 20,331	¥ 1,484,675	¥ 26,085	¥1,510,760

The accompanying notes are an integral part of these statements.

						Thou	ısands of U.	S. Dollars (No	ote 1)				
	Notes	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	Defined retirement benefit plans	Total	Minority interests	Total equity
Balance, March 31, 2013		\$793,733	\$4,959,415	\$ 1,020	\$7,465,166	\$ (178,702)	\$ 80,490	\$ —	\$ (386,941)	\$ -	\$ 12,734,181	\$ 140,585	\$12,874,766
Cash dividends, \$0.58 per share					(318,237)						(318,237)		(318,237)
Net income					1,467,062						1,467,062		1,467,062
Disposal of treasury stock			(1,108)			4,528					3,420		3,420
Purchase of treasury stock						(291,518)					(291,518)		(291,518)
Change in scope of consolidation	2(a)		25,136		49,194						74,330		74,330
Net change in the year							53,789	(68)	505,023	197,542	756,286	112,864	869,150
Balance, March 31, 2014		\$793,733	\$4,983,443	\$ 1,020	\$8,663,185	\$ (465,692)	\$ 134,279	\$ (68)	\$ 118,082	\$ 197,542	\$ 14,425,524	\$ 253,449	\$14,678,973

## CONSOLIDATED STATEMENT OF CASH FLOWS

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries for the year ended March 31, 2014

		Millions	of Yen	Thousands of U.S. Dollars (Note 1)
		2014.3	2013.3	2014.3
Operating activities:				
Income before income taxes and minority interests		¥ 210,225	¥ 176,939	\$2,042,606
Adjustments for:				
Income taxes paid		(66,130)	(66,829)	(642,538)
Depreciation and amortization		49,746	45,463	483,346
Amortization of negative goodwill		(2,648)	(2,464)	(25,729)
Equity in earnings of unconsolidated subsidiaries and affiliated companies		(3,222)	(3,140)	(31,306)
Loss on impairment of long-lived assets		3,399	2,571	33,026
Loss on valuation of investment securities and investments in unconsolidated subsidiaries and affiliated companies		211	4,408	2,050
Changes in assets and liabilities:				
Decrease (increase) in trade receivables		12,392	(47,240)	120,404
Increase in inventories		(1,806)	(5,516)	(17,548)
Increase (decrease) in trade payables		19,552	(3,869)	189,973
Decrease in long-term unearned revenues		(7,714)	(1,864)	(74,951)
Increase in liability for retirement benefits	3	(13,808)	(4,655)	(134,162)
Other, net	3	26,265	25,536	255,198
Net cash provided by operating activities		226,462	119,340	2,200,369
Investing activities:				
Decrease in marketable securities		12,694	4	123,339
Proceeds from sales of property, plant, and equipment		1,188	319	11,543
Purchases of property, plant, and equipment		(48,777)	(50,541)	(473,931)
Purchases of intangible assets	3	(21,166)	(8,914)	(205,655)
Proceeds from sales and redemptions of investment securities		12,351	16,166	120,006
Purchases of investment securities		(4,007)	(11,232)	(38,933)
Purchases of stock of unconsolidated subsidiaries and affiliated companies		(2,378)	(8,750)	(23,105)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	22	(95,356)	(1,539)	(926,505)
Decrease (increase) in short-term investments		59,140	(29,091)	574,620
Payments of loans receivable from unconsolidated subsidiaries and affiliated companies	3	(22,090)	(622)	(214,633)
Other, net	3	(113)	2,971	(1,099)
Net cash used in investing activities		(108,514)	(91,229)	(1,054,353)
Financing activities:				
Increase in short-term borrowings		5,007	1,095	48,649
Proceeds from long-term debt		7,936	3,394	77,108
Repayments of long-term debt		(13,045)	(16,121)	(126,749)
Purchase of treasury stock		(30,003)	(20,002)	(291,518)
Proceeds from disposal of treasury stock		352	248	3,420
Dividends paid		(32,753)	(29,334)	(318,237)
Dividends paid to minority interests in consolidated subsidiaries		(395)	(454)	(3,838)
Other, net		(3,794)	(10,715)	(36,863)
Net cash used in financing activities		(66,695)	(71,889)	(648,028)
Foreign currency translation adjustments on cash and cash equivalents		9,480	6,223	92,111
Net increase (decrease) in cash and cash equivalents		60,733	(37,555)	590,099
Cash and cash equivalents of newly consolidated subsidiaries		9,234	932	89,720
Cash and cash equivalents, beginning of year		347,571	384,194	3,377,099
Cash and cash equivalents, end of year		¥ 417,538	¥ 347,571	\$4,056,918

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries



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 accordance 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 2013 consolidated financial statements to conform to the classifications used in 2014.

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 ¥102.92 to US\$1, the approximate rate of exchange at March 31, 2014. 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, 2014, include the accounts of the Company and its 95 significant (71 as of March 31, 2013) 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, 2013) unconsolidated subsidiary and 16 (13 as of March 31, 2013) affiliated companies are accounted for by the equity method.

During the year ended March 31, 2014, Claris Otsuka Limited (Claris Otsuka), Astex Pharmaceuticals, Inc. (Astex) and one other company were newly included in the scope of consolidation from the fiscal year ended March 31, 2014 as a result of the acquisition of their shares.

Nippon Pharmaceutical Chemicals Co., Ltd. and 24 other companies were newly included in the scope of consolidation from the fiscal year

ended March 31, 2014 due to their increase in materiality.

Chongqing Otsuka Huayi Chemical Co., Ltd. was excluded from the scope of consolidation in the current fiscal year as a result of sales of the shares.

Otsuka America Manufacturing LLC, a previously consolidated subsidiary, was absorbed by Crystal Geyser Water Company, a consolidated subsidiary. Valpiform SAS and one other company, which had been in the scope of consolidation, were absorbed by Nutrition & Nature SAS, a consolidated subsidiary.

Nichiban Co., Ltd. and two other companies were newly included in the scope of equity method application from the current fiscal year due to their increase in materiality.

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 to 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
  - 4) Cancellation of the fair value model of accounting for

- property, plant, and equipment and investment properties and incorporation of the cost model of 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 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 of accounting for property, plant, and equipment and investment properties and incorporation of the cost model of 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 (IP R&D) 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.

The Group acquired 60% of the shares of Claris Otsuka on July 31, 2013 and 100% of shares of Astex on October 11, 2013, and accounted for them by the purchase method of accounting. The related goodwill is systematically amortized over 10 and 20 years, respectively.

#### (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





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

method over the estimated useful lives of the assets, while the straightline 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 two to 65 years for buildings and structures and from two to 30 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 and pension plans

The majority of domestic consolidated subsidiaries have defined benefit pension plans held by jointly founded Otsuka Pharmaceuticals corporate pension fund (a type of fund in multi-employer plans) and defined contributory pension plans. The defined benefit pension plans consists of contributory funded corporate pension plans and lump-sum retirement payments plans. Certain foreign consolidated subsidiaries have contributory funded or unfuned defined benefit pension plans, defined contributory pension plans, or a combination of them.

The projected benefit obligations are attributed to period on a straight line basis. Actuarial gains and losses are amortized on a straight-line basis over five to 20 years within the average remaining service period. Past service costs are amortized on a straight-line basis over five to 23 years within the average remaining service period. Transitional obligations are amortized over five to 15 years.

In May 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 an effective date of April 1, 2000, and the other related practical guidance, and were followed by partial amendments from time to time through 2009.

(1) Under the revised accounting standard, actuarial gains and losses and past service costs that are yet to be recognized in

- profit or loss are recognized within equity (accumulated other comprehensive income), after adjusting for tax effects, and any resulting deficit or surplus is recognized as a liability (liability for retirement benefits) or asset (asset for retirement benefits).
- (2) The revised accounting standard does not change how to recognize actuarial gains and losses and past service costs in profit or loss. Those amounts are recognized in profit or loss over a certain period no longer than the expected average remaining service period of the employees. However, actuarial gains and losses and past service costs that arose in the current period and have not yet been recognized in profit or loss are 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 (see Note 2(v)).
- (3) The revised accounting standard also made certain amendments relating to the method of attributing expected benefit to periods and relating to the discount rate and expected future salary increases.

This accounting standard and the guidance for (1) and (2) above are effective for the end of annual periods beginning on or after April 1, 2013, and for (3) above are effective for the beginning of annual periods beginning on or after April 1, 2014, or for the beginning of annual periods beginning on or after April 1, 2015, subject to certain disclosure in March 2015, both 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 applied the revised accounting standard and guidance for retirement benefits for (1) and (2) above, effective March 31, 2014. As a result, asset for retirement benefits of ¥11,113 million (US\$107,977 thousand) and liability for retirement benefits of ¥8,131 million (US\$79,003 thousand) were recorded as of March 31, 2014, respectively, and accumulated other comprehensive income increased by ¥20,331 million (US\$197,542 thousand), and minority interests increased by ¥56 million (US\$545 thousand) for the year ended March 31, 2014, respectively.

Retirement benefits for directors and audit and supervisory board members of certain domestic consolidated subsidiaries are recorded to state the liability at the amount that would be required if all directors and audit and supervisory board members retired at the consolidated 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 the 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 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 consolidated 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 bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates 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 statement 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.





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

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, prior-period 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.

#### (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 an effective date of April 1, 2000, and the other related practical guidance, and were followed by partial amendments from time to time through 2009.

Major changes are as follows:

(1) Treatment in the consolidated 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 consolidated balance
sheet, and the difference between retirement benefit
obligations and plan assets (hereinafter, "deficit or
surplus"), adjusted by such unrecognized amounts, is
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 any resulting deficit or surplus shall be recognized as a liability (liability for retirement benefits) or asset (asset for retirement benefits).

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

The revised accounting standard does 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 service period of the employees. However, actuarial gains and losses and past service costs that arose in the current period and have not yet been 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.

(3) Amendments relating to the method of attributing expected benefit to periods and relating to the discount rate and expected future salary increases

The revised accounting standard also made certain amendments relating to the method of attributing expected benefit to periods and relating to the discount rate and expected future salary increases.

This accounting standard and the guidance for (1) and (2) above are effective for the end of annual periods beginning on or after April 1, 2013, and for (3) above are effective for the beginning of annual periods beginning on or after April 1, 2014, or for the beginning of annual periods beginning on or after April 1, 2015, subject to certain disclosure in March 2015, both 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 applied the revised accounting standard for (1) and (2) above effective March 31, 2014, and expects to apply (3) above from April 1, 2014, and is in the process of measuring the effects of applying the revised accounting standard for (3) above in future applicable periods.

## (Accounting Standards for Business Combinations and Consolidated Financial Statements)

On September 13, 2013, the ASBJ issued revised ASBJ Statement No. 21, "Accounting Standard for Business Combinations," revised ASBJ Statement No.7, "Accounting Standard for Business Divestitures," revised ASBJ Guidance No. 10, "Guidance on Accounting Standards for Business Combinations and Business Divestitures," and revised ASBJ Statement No. 22, "Accounting Standard for Consolidated Financial Statements." Major accounting changes are as follows:

(1) Transactions with noncontrolling interest A parent's ownership interest in a subsidiary might change if the parent purchases or sells ownership interests in its subsidiary. The carrying amount of minority interest is adjusted to reflect the change in the parent's ownership interest in its subsidiary while the parent retains its controlling interest in its subsidiary. Under the current accounting standard, any difference between the fair value of the consideration received or paid and the amount by which the minority interest is adjusted is accounted for as an adjustment of goodwill or as profit or loss in the consolidated statement of income. Under the revised accounting standard, such difference shall be accounted for as capital surplus as long as the parent retains control over its subsidiary.

- (2) Presentation of the consolidated balance sheet In the consolidated balance sheet, "minority interest" under the current accounting standard will be changed to "noncontrolling interest" under the revised accounting standard.
- (3) Presentation of the consolidated statement of income
  In the consolidated statement of income, "income before
  minority interest" under the current accounting standard will
  be changed to "net income" under the revised accounting
  standard, and "net income" under the current accounting
  standard will be changed to "net income attributable to
  owners of the parent" under the revised accounting standard.
- (4) Provisional accounting treatments for a business combination If the initial accounting for a business combination is incomplete by the end of the reporting period in which the business combination occurs, an acquirer shall report in its consolidated financial statements provisioned amounts for the items for which the accounting is incomplete. Under the current accounting standard guidance, the impact of adjustments to provisional amounts recorded in a business combination on profit or loss is recognized as profit or loss in the year in which the measurement is completed. Under the revised accounting standard guidance, during the measurement period, which shall not exceed one year from the acquisition, the acquirer shall retrospectively adjust the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date and that would have affected the measurement of the amounts recognized as of that date. Such adjustments shall be recognized as if the accounting for the business combination had been completed at the acquisition date.
- (5) Acquisition-related costs

Acquisition-related costs are costs, such as advisory fees or professional fees, which an acquirer incurs to effect a business combination. Under the current accounting standard, the acquirer accounts for acquisition-related costs by including them in the acquisition costs of the investment. Under the revised accounting standard, acquisition-related costs shall be accounted for as expenses in the periods in which the costs are incurred.





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

The above accounting standards and guidance for "transactions with noncontrolling interest," "acquisition-related costs" and "presentation changes in the consolidated financial statements" are effective for the beginning of annual periods beginning on or after April 1, 2015. Earlier application is permitted from the beginning of annual periods beginning on or after April 1, 2014, except for the presentation changes in the consolidated financial statements. In case of earlier application, all accounting standards and guidance above, except for the presentation changes, should be applied simultaneously. Either retrospective or prospective application of the revised accounting standards and guidance for "transactions with noncontrolling interest" and "acquisition-related costs" is permitted. In retrospective application of the revised standards and guidance for "transactions with noncontrolling interest" and "acquisition-related costs," accumulated effects of retrospective adjustments for all "transactions with noncontrolling interest" and "acquisition-related costs" which occurred in the past shall be reflected as adjustments to the beginning balance of capital surplus and retained earnings for the year of the first-time application.

In prospective application, the new standards and guidance for "transactions with noncontrolling interest" and "acquisition-related costs" shall be applied prospectively from the beginning of the year of the first-time application. The changes in presentation shall be applied to all periods presented in consolidated financial statements containing the first-time application of the revised standards and guidance.

The revised standards and guidance for "provisional accounting treatments for a business combination" is effective for a business combination which will occur on or after the beginning of annual periods beginning on or after April 1, 2015. Earlier application is permitted for a business combination which will occur on or after the beginning of annual periods beginning on or after April 1, 2014.

The Company expects to apply the revised accounting standards and guidance from the beginning of the annual period beginning on January 1, 2016, and is in the process of measuring the effects of applying the revised accounting standards and guidance in future applicable periods.

#### 3. Changes in method of presentation

## (Change in the method of presentation for a component of cash flows)

Previously, "Increase in liability for retirement benefits" was included in "Other, net" of operating activities in the consolidated statement of cash flows. However, as "Increase in liability for retirement benefits" is material in the current year, the increase is stated separately in operating activities. As a result of the change, in the consolidated statement of cash flows for the prior fiscal year, \$20,881 million was separated into \$(4,655) million of "Increase in

liability for retirement benefits" and ¥25,536 million of "Other, net" of operating activities (see Note 10, Retirement and pension plans).

Previously, "Purchases of intangible assets" and "Payments of loans receivable from unconsolidated subsidiaries and affiliated companies" were included in "Other, net" of investing activities in the consolidated statement of cash flows. However, as "Purchases of intangible assets" and "Payments of loans receivable from unconsolidated subsidiaries and affiliated companies" are material in the current year, they are stated separately in investing activities. As a result of the changes, in the consolidated statement of cash flows for the prior fiscal year, ¥(6,565) million was separated into ¥(8,914) million of "Purchases of intangible assets," ¥(622) million of "Payments of loans receivable from unconsolidated subsidiaries and affiliated companies" and ¥2,971 million of "Other, net" of investing activities.

#### 4. Business combination

Significant business combinations for year ended March 31, 2014 were as follows:

#### (Acquisition of Claris Otsuka)

On July 31, 2013, Otsuka Pharmaceutical Factory, Inc., a consolidated subsidiary, acquired 60% of the shares of Claris Otsuka.

Claris Otsuka is a company in India, primarily dedicated to manufacturing and marketing of IV solutions and clinical nutrition products. The IV solutions market in India is expected to benefit from demand expansion driven by its economic growth and improvement in middle class incomes, combined with development of insurance systems and the increase in the number of medical institutions. In the future, India is expected to become one of the world's largest pharmaceutical markets. Claris Otsuka will meet the increasing demand for IV solutions in India.

The results of operations for Claris Otsuka are included in the Company's consolidated statement of income from the date of acquisition.

The Company accounted for this business combination by the purchase method of accounting.

The purchase price was ¥13,315million (US\$129,372 thousand) in cash and other cost associated with the acquisition including advisory fee was ¥133 million (US\$1,291 thousand). The total cost of acquisition has been allocated to the assets acquired and the liabilities assumed based on their respective fair values. Goodwill recorded in connection with the acquisition totaled ¥3,435 million (US\$33,375 thousand).

The estimated fair values of the assets acquired and the liabilities assumed at the acquisition date are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥ 1,105	\$ 10,736
Noncurrent assets	17,609	171,094
Total assets acquired	18,724	181,830
Current liabilities	(1,790)	(17,392)
Long-term liabilities	(51)	(496)
Total liabilities assumed	(1,841)	(17,888)
Net assets acquired	¥ 16,873	\$163,942

The condensed pro forma consolidated statement of income for the year ended March 31, 2014, assuming these business combinations had been completed as of April 1, 2013, the current fiscal year, is omitted since it is immaterial.

#### (Acquisition of Astex)

On October 11, 2013, Autumn Acquisition Corporation (a whollyowned Special Purpose Acquisition Company) acquired 100% of shares of Astex.

Astex is a bio-venture company, primarily dedicated to research and development and commercialization of pharmaceuticals in cancer area, with a fragment-based drug discovery research center in Cambridge, England and a clinical research and development function in California, United States. The Otsuka Group hopes to be able to provide innovative therapeutics with new working mechanisms going forward by combining Astex's fragment-based drug discovery technology with the Group's strength in R&D in the central nervous system area that produced *ABILIFY*.

On the clinical R&D front, through this acquisition of Astex, which excels in clinical R&D as well, the Group will strengthen its anticancer drug R&D position and expand its portfolio in the cancer area.

The results of operations for Astex are included in the Company's consolidated statements of income from the date of acquisition.

The Company accounted for this business combination by the purchase method of accounting.

The purchase price was \$78,615million (US\$763,846 thousand) in cash and other cost associated with the acquisition was \$7,474 million (US\$72,620 thousand). The total cost of acquisition has been allocated to the assets acquired and the liabilities assumed based on their respective fair values. Goodwill recorded in connection with the acquisition totaled \$29,219 million (US\$283,900 thousand).

The estimated fair values of the assets acquired and the liabilities assumed at the acquisition date are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥15,041	\$146,143
Noncurrent assets (Note)	57,145	555,237
Total assets acquired	72,186	701,380
Current liabilities	(4,990)	(48,484)
Long-term liabilities	(10,326)	(100,330)
Total liabilities assumed	(15,316)	(148,814)
Net assets acquired	¥56,870	\$552,566

Note: The amount allocated to intangible asset other than Goodwill totaled ¥56,272 million (US\$546,755 thousand), including IP R&D assets ¥27,883 million (US\$270,919 thousand) and assets related with contracts and others ¥28,389 million (US\$275,836 thousand). The weighted average amortization period of the assets related with contracts and others is seven years.

The condensed pro forma consolidated statement of income for the year ended March 31, 2014, assuming these business combinations had been completed as of April 1, 2013, the current fiscal year, is omitted since it is immaterial.

There were no material business combinations for the year ended March 31, 2013.

#### 5. Short-term investments

Short-term investments as of March 31, 2014 and 2013, consisted of the following:

	Million	Thousands of U.S. Dollars	
	2014.3	2013.3	2014.3
Time deposits	¥ 97,279	¥152,074	\$945,190
Other	_	20,000	_
Total	¥ 97,279	¥172,074	\$945,190

#### 6. Securities

Securities as of March 31, 2014 and 2013, consisted of the following:

	Million	Thousands of U.S. Dollars	
	2014.3	2013.3	2014.3
Current:			
Government and corporate bonds	¥ 50,159	¥ 32,504	\$ 487,359
Other	8,297	_	80,616
Total current	¥ 58,456	¥ 32,504	\$ 567,975
Noncurrent:			
Marketable equity securities	¥ 63,894	¥ 53,170	\$ 620,812
Government and corporate bonds	38,182	51,002	370,987
Other	14,543	14,610	141,304
Total noncurrent	¥116,619	¥118,782	\$1,133,103

The costs and aggregate fair values of marketable and investment securities at March 31, 2014 and 2013, were as follows:

	Millions of Yen				
March 31, 2014					
Securities classified as:					
Available for sale:					
Equity securities	¥50,981	¥23,012	¥1,802	¥72,191	
Other	_	_	_	_	
Held to maturity	88,341	261	18	88,584	





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

	Millions of Yen				
March 31, 2013					
Securities classified as:					
Available for sale:					
Equity securities	¥39,878	¥14,870	¥1,578	¥53,170	
Other	_	_	_	_	
Held to maturity	83,506	490	80	83,916	

	Thousands of U.S. Dollars			
March 31, 2014	Cost			
Securities classified as:				
Available for sale:				
Equity securities	\$495,346	\$223,591	\$17,509	\$701,428
Other	_	_	_	_
Held to maturity	858,346	2,536	175	860,707

Available-for-sale securities and held-to-maturity securities whose fair values are not determinable are disclosed in Note 18(4)(b).

The information of available-for-sale securities, which were sold during the years ended March 31, 2014 and 2013, was as follows:

Mayeb 21, 2014		Millions of Yen		
March 31, 2014	Proceeds			
Available for sale:				
Equity securities	¥844	¥302	¥—	
Total	¥844	¥302	¥—	

March 21, 2012		Millions of Yen		
March 31, 2013				
Available for sale:				
Equity securities	¥21	¥4	¥—	
Total	¥21	¥4	¥—	

Mayeb 21, 2014	Thousands of U.S. Dollars			
March 31, 2014				
Available for sale:				
Equity securities	\$8,201	\$2,934	\$—	
Total	\$8,201	\$2,934	\$—	

The impairment losses on equity securities for the years ended March 31, 2014 and 2013, were  $\pm$ 211 million (US\$2,050 thousand) and  $\pm$ 4,408 million, respectively.

#### 7. Inventories

Inventories at March 31, 2014 and 2013, consisted of the following:

	Million:	Thousands of U.S. Dollars	
	2014.3	2013.3	2014.3
Finished products and merchandise	¥ 83,820	¥ 71,243	\$ 814,419
Work in process	30,626	25,842	297,571
Raw materials and supplies	37,417	35,267	363,554
Total	¥ 151,863	¥132,352	\$1,475,544

#### 8. Long-lived assets

The Group reviewed its long-lived assets for impairment as of March 31, 2014. As a result, the Group recognized an impairment loss of ¥3,399 million (US\$33,026 thousand) due to a decline in profitability in each business segment, related to certain business properties operating at lower-than-expected rates of 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, 2014 and 2013, were as follows:

Pharmaceuticals:	Millions of Yen		Thousands of U.S. Dollars
Thaimaccarcais.	2014.3	2013.3	2014.3
Buildings and structures	¥11	¥ 831	\$107
Machinery and equipment	5	109	49
Other	17	191	165
Total	¥33	¥ 1.131	\$321

Nutraceuticals:	Million	Millions of Yen	
	2014.3	2013.3	2014.3
Intangible assets	¥ 732	¥ —	\$ 7,112
Buildings and structures	255	37	2,478
Machinery and equipment	1,811	889	17,596
Other	46	28	447
Total	¥ 2.844	¥954	\$27,633

Consumer products:	Millions of Yen		Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Buildings and structures	¥126	¥ —	\$1,224
Machinery and equipment	300	166	2,915
Other	33	48	321
Total	¥459	¥214	\$4,460

Other:	Millions of Yen		Thousands of U.S. Dollars
o dien	2014.3	2013.3	2014.3
Land	¥8	¥189	\$78
Buildings and structures	_	8	_
Machinery and equipment	_	4	_
Other	_	_	_
Total	¥8	¥201	\$78

Corporate:	Millions of Yen		Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Land	¥55	¥71	\$534
Other	_	_	_
Total	¥55	¥71	\$534

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 at their value in use with discount rate, primarily 7.5%, or net selling price at disposition. The recoverable amount of the impaired idle assets was measured at net realizable value as determined based on the net selling price or on real estate appraisals.

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

Short-term borrowings at March 31, 2014 and 2013, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Secured loans from banks and financial institutions			
With a weighted-average interest rate of 1.5% (2014)	¥ 164	¥ —	\$ 1,593
Unsecured loans from banks and financial institutions			
With a weighted-average interest rate of 1.3% (2014) and with a weighted-average interest rate of 1.1% (2013)	51,129	39,046	496,784
Total	¥ 51,293	¥ 39,046	\$498,377

Long-term debt at March 31, 2014 and 2013, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Secured loans from banks and financial institutions			
Due 2014 to 2022, with a weighted- average interest rate of 2.3% (2014) and due 2013 to 2022, with a weighted- average interest rate of 1.7% (2013)	¥ 1,495	¥ 629	\$ 14,526
Unsecured loans from banks and financial institutions			
Due 2014 to 2021, with a weighted- average interest rate of 1.2% (2014) and due 2013 to 2033, with a weighted- average interest rate of 0.8% (2013)	14,920	18,367	144,967
Unsecured straight bonds by a consolidated subsidiary			
Due 2014 to 2016, with a weighted- average interest rate of 0.8% (2014) and due 2013 to 2016, with a weighted- average interest rate of 0.9% (2013)	280	370	2,721
Lease liabilities			
Secured	_	38	_
Unsecured	7,930	8,412	77,050
Total	24,625	27,816	239,264
Less-portion due within one year			
Loans	2,133	12,744	20,725
Straight bonds	180	150	1,749
Lease liabilities	2,238	2,590	21,745
Long-term debt, less current portion	¥ 20,074	¥ 12,332	\$195,045

Annual maturities of long-term debt at March 31, 2014, were as follows:

Years ending March 31	Millions of Yen	Thousands of U.S. Dollars
2015	¥ 4,551	\$ 44,219
2016	5,684	55,227
2017	7,320	71,123
2018	3,686	35,814
2019	1,063	10,328
2020 and thereafter	2,321	22,553
Total	¥ 24,625	\$239,264

The carrying amounts of assets pledged as collateral for long-term debt at March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Cash and cash equivalents	¥ 1,039	\$ 10,095
Receivables-trade accounts	852	8,278
Inventories	3,019	29,333
Other current assets	7	69
Property, plant, and equipment - net of accumulated depreciation	6,430	62,476
Total	¥ 11,347	\$110,251

#### 10. Retirement and pension plans

The majority of domestic consolidated subsidiaries have defined benefit pension plans held by jointly founded Otsuka Pharmaceuticals corporate pension fund (a type of fund in multiemployer plans) and defined contributory pension plans. The defined benefit pension plans consists of contributory funded corporate pension plans and lump-sum retirement payments plans. Certain foreign consolidated subsidiaries have contributory funded or unfuned defined benefit pension plans or defined contributory pension plans, or a combination of them.

The liability for employees' retirement benefits at March 31, 2014 and 2013, consisted of the following:

#### Year Ended March 31, 2014

(1) The changes in defined benefit obligation for the year ended March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Balance at beginning of year	¥194,330	\$1,888,166
Current service cost	7,462	72,503
Interest cost	3,616	35,134
Actuarial gains	(3,312)	(32,180)
Benefits paid	(8,633)	(83,881)
Change in scope of consolidation	1,501	14,584
Foreign currency translation adjustment	2,962	28,780
Others	233	2,263
Balance at end of year	¥198,159	\$1,925,369

(2) The changes in plan assets for the year ended March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Balance at beginning of year	¥171,107	\$1,662,524
Expected return on plan assets	4,779	46,434
Actuarial gains	12,462	121,084
Contributions from the employer	17,467	169,714
Benefits paid	(7,729)	(75,097)
Change in scope of consolidation	1,232	11,970
Foreign currency translation adjustment	1,796	17,450
Others	27	264
Balance at end of year	¥201,141	\$1,954,343

(3) Reconciliation between the liability (asset) recorded in the consolidated balance sheet and the balances of defined benefit obligation and plan assets

	Millions of Yen	Thousands of U.S. Dollars
Funded defined benefit obligation	¥ 195,587	\$ 1,900,379
Plan assets	(201,141)	(1,954,343)
	(5,554)	(53,964)
Unfunded defined benefit obligation	2,572	24,990
Net asset arising from defined benefit obligation	(2,982)	(28,974)
Liability for retirement benefits	8,131	79,003
Asset for retirement benefits	(11,113)	(107,977)
Net asset arising from defined benefit obligation	¥ (2,982)	\$ (28,974)





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

(4) The components of net periodic benefit costs for the year ended March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Service cost	¥ 7,462	\$72,503
Interest cost	3,616	35,134
Expected return on plan assets	(4,779)	(46,434)
Amortization of past service cost	(3,049)	(29,625)
Recognized actuarial losses	524	5,091
Amortization of transitional obligation	15	146
Extra retirement payments	240	2,332
Net periodic benefit costs	¥ 4,029	\$39,147

(5) Accumulated other comprehensive income on defined retirement benefit plans as of March 31, 2014

	Millions of Yen	Thousands of U.S. Dollars
Unrecognized past service cost	¥ 12,164	\$118,189
Unrecognized actuarial losses	19,305	187,573
Unrecognized transitional obligation	(44)	(428)
Total	¥31,425	\$305,334

- (6) Plan assets
  - a. Components of plan assets Plan assets consisted of the following:

Debt investments	41%
Equity investments	34%
Others	25%
Total	100%

- b. Method of determining the expected rate of return on plan assets The expected rate of return on plan assets is determined considering the long-term rates of return which are expected currently and in the future from the various components of the plan assets.
- (7) Assumptions used for the year ended March 31, 2014, were set forth as follows:

Discount rate	1.10% - 9.25%
Expected rate of return on plan assets	2.00% - 8.00%

(8) Contributions to defined contribution pension plan for the year ended March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Contributions to defined contribution pension plan	¥3,639	\$35,358

### Year Ended March 31, 2013

The liability (asset) for retirement benefits at March 31, 2013, consisted of the following:

	Millions of Yen
Projected benefit obligation	¥194,330
Fair value of plan assets	(171,107)
Unrecognized past service cost	14,802
Unrecognized actuarial gain	2,485
Unrecognized transitional obligation	(15)
Prepaid pension cost	76
Net liability	¥ 40,571

The components of net periodic benefit costs for the year ended March 31, 2013, are as follows:

	Millions of Yen
Service cost	¥ 7,633
Interest cost	4,187
Expected return on plan assets	(3,829)
Amortization of past service cost	(1,218)
Recognized actuarial loss	4,846
Amortization of transitional obligation	6
Net periodic benefit costs	11,625
Additional benefit	369
Contributions to defined contribution pension plan	2,408
Total	¥ 14,402

Assumptions used for the year ended March 31, 2013, are set forth as follows:

Discount rate	1.10%-6.00%
Expected rate of return on plan assets	2.00%-8.00%
Amortization period of past service cost	5-23 years
Recognition period of actuarial gain/loss	5-22 years
Amortization period of transitional obligation	5-15 years

# 11. 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 outside audit and supervisory board member, (3) the company must have an audit and supervisory board, 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.

## 12. Stock options

The stock options outstanding as of March 31, 2014, are as follows:

Stock Option		Number of Options Granted		Exercise Price	Exercise Period
2010 Stock Option No. 1	11 Company directors	490,000 shares	July 22, 2010	¥1 (\$0)	From July 23, 2012 to July 31, 2015
	Four audit and supervisory board members	32,000 shares	July 22, 2010	¥2,100 (\$20)	From July 23, 2012 to July 31, 2015
2010 Stock Option No. 4	Five Company corporate officers, 31 subsidiary directors, four subsidiary audit and supervisory board members, and 21 subsidiary corporate officers	620,000 shares	July 22, 2010	¥2,100 (\$20)	From July 23, 2012 to July 31, 2015

### The stock option activity is as follows:

For the year ended March 31, 2014		2010 Stock Option No. 2	2010 Stock Option No. 4
Nonvested:			
March 31, 2013 – Outstanding	_	_	_
Granted	_	_	_
Canceled	_	_	_
Vested	_	_	_
March 31, 2014 – Outstanding	_		
Vested:			
March 31, 2013 – Outstanding	50,000 shares	27,400 shares	506,565 shares
Vested	_	_	_
Exercised	_	9,700 shares	157,770 shares
Canceled	_	_	_
March 31, 2014 – Outstanding	50,000 shares	17,700 shares	348,795 shares
		V 2 400	
Exercise price	¥ 1	¥ 2,100	¥ 2,100
	(\$ 0)	(\$20)	(\$20)
Average stock price at exercise	¥	¥ 3,134	¥ 3,134
•	\$—	(\$30)	(\$30)
Fair value price at grant date	¥ 2,099	¥ _—	¥ _—
	(\$20)	\$—	<u> </u>

# The assumptions used to measure the 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, 2014 and 2013, was ¥516 million (US\$5,014 thousand) and ¥806 million, respectively.
- 2) The total intrinsic value of the stock option rights on the exercise date for the fiscal year ended March 31, 2014 and 2013 was ¥151 million (US\$1,467 thousand) and ¥1,383 million, respectively.

### 13. Income taxes

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in aggregate, resulted in normal effective statutory tax rates of approximately 38.0% for the fiscal years ended March 31, 2014 and 2013, respectively.

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, 2014 and 2013, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Deferred tax assets:			
Liability for retirement benefits	¥ 2,745	¥ 13,577	\$ 26,671
Unrealized intercompany profits from inventories	24,570	18,946	238,729
Accrued expenses	12,329	10,685	119,792
Accrued enterprise tax	4,473	3,368	43,461
Tax loss carryforwards	29,451	15,958	286,154
Research and development expenses	34,943	14,992	339,516
Loss on devaluation of investment securities	3,921	7,792	38,098
Loss on impairment of long-lived assets	3,920	3,334	38,088
Long-term unearned revenue	11,639	9,929	113,088
Other	9,170	8,559	89,099
Less valuation allowance	(30,976)	(30,132)	(300,972)
Total deferred tax assets	106,185	77,008	1,031,724
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	7,542	4,576	73,280
Asset for retirement benefits	3,964	_	38,515
Unrealized gain on full revaluation resulting from inclusion of consolidated subsidiaries	26,643	6,152	258,871
Revaluation of brands	4,245	3,656	41,246
Other	9,099	6,692	88,409
Total deferred tax liabilities	51,493	21,076	500,321
Net deferred tax assets	¥ 54,692	¥ 55,932	\$ 531,403







Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

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, 2014 and 2013, was as follows:

	2014.3	2013.3
Normal effective statutory tax rate	38.0%	38.0%
Tax credit for research and development expenses	(15.2)	(10.1)
Reduction of ending deferred tax balance due to change in statutory tax rate	0.8	_
Expenses not deductible for income tax purposes	1.2	1.3
Valuation allowance	1.2	1.0
Difference in statutory tax rate of subsidiaries	0.0	(0.3)
Equity in earnings of affiliated companies	(0.1)	(0.3)
Other – net	1.5	0.8
Actual effective tax rate	27.4%	30.4%

New tax reform laws enacted in 2014 in Japan changed the normal effective statutory tax rate for the fiscal year beginning on or after April 1, 2014, from approximately 38.0% to 35.6%. The effect of this change was to decrease deferred tax assets in the consolidated balance sheet as of March 31, 2014, by ¥1,631 million (US\$15,847 thousand) and to increase income taxes—deferred in the consolidated statement of income for the year then ended by ¥1,631 million (US\$15,847 thousand).

At March 31, 2014, certain consolidated subsidiaries had tax loss carryforwards aggregating ¥29,450 million

(US\$286,145 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
2015	¥ 1,454	\$ 14,127
2016	785	7,627
2017	1,612	15,663
2018	1,616	15,702
2019 and thereafter	23,983	233,026
Total	¥ 29,450	\$286,145

# 14. Up-front licensing payments received

Net sales recognized as revenue from the up-front licensing payments received for the years ended March 31, 2014 and 2013, were as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	2014.3	2013.3	2014.3
Up-front licensing payments received	¥21,972	¥41,512	\$213,486

# 15. Selling, general, and administrative expenses

Selling, general, and administrative expenses for the years ended March 31, 2014 and 2013, consisted of the following:

	Million	of Yen	Thousands of U.S. Dollars
	2014.3 2013.3		2014.3
Sales promotion expenses	¥192,031	¥156,214	\$1,865,828
Personnel expenses	124,042	103,691	1,205,227
Depreciation	16,896	14,465	164,166
Amortization of goodwill	3,714	4,848	36,086
Research and development expenses	249,010	192,364	2,419,452
Other	226,731	182,982	2,202,984
Selling, general, and administrative expenses	¥812,424	¥654,564	\$7,893,743

### 16. Leases

The Group leases certain assets, mainly machinery and equipment.

The future minimum lease payments under noncancelable operating leases at March 31, 2014, were as follows:

2014.3	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 4,474	\$ 43,470
Due after one year	14,762	143,432
Total	¥ 19,236	\$ 186,902

# 17. Related-party transactions

- (1) The material related-party transactions of March 31, 2014 are as follows:
  - (a) Related-party transactions between the Company and related parties

Time	Nama	Relationship	Ownership (Owned)	Transaction detail	Transactio	n amount
Type					Millions of Yen	Thousands of U.S. Dollars
Audit and supervisory board member	Yasuhisa Katsuta	Audit and supervisory board member of the Company	(Owned) Direct 0.0%	Exercise of stock option	¥13	\$126
Close family member of Director	Kyoichi Komatsu	Chairman and Representative Director of Otsuka Pharmaceutical Factory, Inc.	(Owned) Direct 0.0%	Exercise of stock option	15	146
Director of significant subsidiaries	Koichi Matsuda	Vice President, Representative Director of Taiho Pharmaceutical Co., Ltd.	(Owned) Direct 0.0%	Exercise of stock option	12	117

(b) Related-party transactions between subsidiary (Otsuka Medical Devices Co., Ltd.) and related parties

						Transaction an	nount (Note 2)		Balance at year-end (Note 2)	
Type Name		Contents of Business	Ownership (Owned) percentage	Transaction detail	Millions of Yen	Thousands of U.S. Dollars		Millions of Yen	Thousands of U.S. Dollars	
					Loans	¥20,972	\$203,770	Receivables: Unconsolidated subsidiaries and affiliated companies (short-term loan receivable)	¥16,467	\$159,998
	affiliated ompany	Microport Scientific Corporation	Medical business (Holding company)	(Owned) Indirect 33.3%	(Note 3,4,5)	¥20,972	\$203,770	Investments in and advances to unconsolidated subsidiareis and affiliated companies (long-term loan receivable)	4,117	40,002
					Interest income (Note 3)	62	602	Other current assets (accrued interest)	62	602

- (2) The material related-party transactions of March 31, 2013 are as follows:
  - (a) Related-party transactions between the Company and related parties

Туре	Name	Relationship	Ownership (Owned) percentage	Transaction detail (Note 1)	Transaction amount Millions of Yen
The Company director	Tatsuo Higuchi	President and Representative Director, chief executive officer of the Company	(Owned) Direct 0.0%	Exercise of stock option	¥145
The Company director	Ichiro Otsuka	Senior Vice President of the Company	(Owned) Direct 0.2%	Exercise of stock option	121
The Company director	Atsumasa Makise	Senior Managing Director of the Company	(Owned) Direct 0.0%	Exercise of stock option	97
The Company director	Yoshiro Matsuo	Managing Director of the Company	(Owned) Direct 0.0%	Exercise of stock option	97
The Company director	Yujiro Otsuka	Executive Director of the Company	(Owned) Direct 0.0%	Exercise of stock option	97
The Company director	Yukio Kobayashi	Executive Director of the Company	(Owned) Direct 0.3%	Exercise of stock option	97
Director of significant subsidiaries	Taro Iwamoto	President, Representative Director of Otsuka Pharmaceutical Co., Ltd.	(Owned) Direct 0.0%	Exercise of stock option	121
Director of significant subsidiaries	Masayuki Umeno	Vice President , Representative Director of Otsuka Pharmaceutical Co., Ltd.	(Owned) Direct 0.0%	Exercise of stock option	121
Director of significant subsidiaries	Kyoichi Komatsu	Chairman and Representative Director of Otsuka Pharmaceutical Factory, Inc.	(Owned) Direct 0.0%	Exercise of stock option	12
Director of significant subsidiaries	Katsuya Yamasaki	Chairman , Representative Director of Otsuka Warehouse Co., Ltd.	(Owned) Direct 0.0%	Exercise of stock option	97
Director of significant subsidiaries	Sadanobu Tobe	Vice Chairman of Otsuka Foods Co., Ltd.	(Owned) Direct 0.0%	Exercise of stock option	121
Director of significant subsidiaries	Noriko Tojo	Executive Director of Pharmavite LLC	(Owned) Direct 0.0%	Exercise of stock option	97

Туре	Name	Relationship	Ownership (Owned) percentage	Transaction detail (Note 6)	Transaction amount Millions of Yen
Director of significant subsidiaries	Masayuki Kobayashi	President of Taiho Pharmaceutical Co., Ltd.	(Owned) Direct 0.0%	Payment of consulting fee	¥13
Director of significant subsidiaries	Katsuya Yamasaki	Chairman , Representative Director of Otsuka Warehouse Co., Ltd.	(Owned) Direct 0.0%	Payment of consulting fee	12
Director of significant subsidiaries	Noriko Tojo	Executive Director of Pharmavite LLC	(Owned) Direct 0.0%	Payment of consulting fee	11

# (b) Related-party transactions between subsidiary (Otsuka Chemical Co., Ltd.) and related parties

Туре		Relationship	Ownership (Owned) percentage	Transaction detail (Note 6)	Transaction amount Millions of Yen
Director of significant subsidiaries	Sadanobu Tobe	Vice Chairman of Otsuka Foods Co., Ltd.	(Owned) Direct 0.0%	Payment of consulting fee	¥12
Officer and his/her close family member	Isao Otsuka	Special advisor of Otsuka Chemical Co., Ltd.	(Owned) Direct 0.0%	Payment of consulting fee	12

#### Notes:

- Presented here are the exercising of rights in the current fiscal year of stock options granted by resolution at the annual shareholders meeting held on June 29, 2010. The transaction amount represents the carrying amount at the time of treasury stock disposal.
- 2. Excluding consumption tax.
- 3. Interest rate is mutually agreed upon based on market rates.
- 4. Otsuka Medical Devices Co., Ltd. accept business-related assets, including inventories and securities from subsidiaries of Microport Scientific Corporation as collateral for loans. Transaction amount of collaterall equals to the balance of receivables as of March 31, 2014
- Part of loans includes the conversion rights to the Microport Scientific Corporation stock.
- Payment is decided by agreement between the two parties based on the details of the consulting agreement.

# 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,





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

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 19 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 the early stages. 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 19 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 loans payable and bonds payable. Please see Note 19 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 19 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, 2014	Carrying amount	Fair value	Unrealized gain
Cash and cash equivalents	¥ 417,538	¥ 417,538	¥ —
Short-term investments	97,279	97,279	_
Receivables	362,441	362,441	_
Marketable and investment securities	160,532	160,775	243
Investments in and advances to unconsolidated subsidiaries and affiliated companies	42,940	93,042	50,102
Total	¥1,080,730	¥ 1,131,075	¥ 50,345
Short-term borrowings	¥ 51,293	¥ 51,293	¥ —
Payables	223,750	223,750	_
Income tax payable	51,064	51,064	_
Long-term debt (excluding straight bonds issued by a consolidated subsidiary and lease liabilities)	16,415	16,404	(11)
Total	¥ 342,522	¥ 342,511	¥ (11)

		Millions of Yen	
March 31, 2013			
Cash and cash equivalents	¥ 347,571	¥ 347,571	¥ —
Short-term investments	172,074	172,074	_
Receivables	332,936	332,936	_
Marketable and investment securities	136,676	137,086	410
Investments in and advances to unconsolidated subsidiaries and affiliated companies	30,805	89,625	58,820
Total	¥1,020,062	¥1,079,292	¥59,230
Short-term borrowings Payables	¥ 39,046 169,293	¥ 39,046 169,293	¥ —
Income tax payable	33,515	33,515	_
Long-term debt (excluding straight bonds issued by a consolidated subsidiary and lease liabilities)	18,996	19,023	27
Total	¥ 260,850	¥ 260,877	¥ 27

March 31, 2014				
Cash and cash equivalents	\$ 4,056,918	\$ 4,056,918	\$ —	
Short-term investments	945,190	945,190	_	
Receivables	3,521,580	3,521,580	_	
Marketable and investment securities	1,559,774	1,562,135	2,361	
Investments in and advances to unconsolidated subsidiaries and affiliated companies	417,217	904,023	486,806	
Total	\$10,500,679	\$10,989,846	\$489,167	
Short-term borrowings Payables Income tax payable Long-term debt (excluding straight bonds	\$ 498,377 2,174,019 496,152	\$ 498,377 2,174,019 496,152	\$ — — —	
issued by a consolidated subsidiary and lease liabilities)	159,493	159,386	(107)	
Total	\$ 3,328,041	\$ 3,327,934	\$ (107)	

# Cash and cash equivalents, short-term investments, and receivables

The carrying values of cash and cash equivalents, short-term investments, and receivables approximate fair value because of their short maturities.

## Marketable and investment securities and investments in and advances to 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 6.

### 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.

# 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 19.

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

	Millions	Thousands of U.S. Dollars	
		Carrying amount	
	2014.3	2013.3	2014.3
Investments in and advances to unconsolidated subsidiaries and affiliated companies	¥149,882	¥157,458	\$1,456,296
Investment securities	14,543	14,610	141,304

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

	Millions of Yen			
March 31, 2014				Due after 10 years
Cash and cash equivalents	¥417,538	¥ —	¥ —	¥ —
Short-term investments	97,279	_	_	_
Receivables	361,989	1,046	7	1
Marketable and investment securities:				
Held-to-maturity securities	50,162	35,686	1,500	1,000
Available-for-sales securities	67,804	_	_	_
Total	¥994,772	¥36,732	¥1,507	¥1,001

			f U.S. Dollars		
March 31, 2014					
Cash and cash equivalents	\$4,056,918	\$ —	\$ —	\$ —	
Short-term investments	945,190	_	_	_	
Receivables	3,517,188	10,163	68	10	
Marketable and investment securities:					
Held-to-maturity securities	487,388	346,735	14,574	9,716	
Available-for-sales securities	658,804	_	_	_	
Total	\$9,665,488	\$356,898	\$14,642	\$9,726	

Please see Note 9 for annual maturities of long-term debt, obligations under finance leases and straight bonds.

### 19. 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 actual demand of 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, 2014 and 2013, are as follows:

	Millions of Yen			
At March 31, 2014				Unrealized loss
Foreign currency forward contracts:				
Buying U.S. \$	¥ 574	¥ 568	¥ (7)	¥ (7)
Buying Euro	494	490	(4)	(4)
Buying JP ¥	107	6	(3)	(3)
Selling U.S. \$	200	_	(11)	(11)
Total	¥1,375	¥1,064	¥(25)	¥(25)

	Millions of Yen				
At March 31, 2013					
Foreign currency forward contracts:					
Buying U.S. \$	¥ 646	¥—	¥(1)	¥(1)	
Buying Euro	556	_	(3)	(3)	
Buying JP ¥	20	_	_	_	
Total	¥1,222	¥—	¥(4)	¥ (4)	



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

Foreign currency forward contracts: Buying U.S. \$ \$ 5.577 \$ 5.519 \$ (68) \$ (68) Buying Euro 4,800 4,761 (39) (39) Buying JP ¥ 1,040 58 (29)(29) Selling U.S. \$ 1,943 (107) (107)\$13,360 \$10,338 \$ (243) \$ (243) Total

Derivative transactions to which hedge accounting is applied at March 31, 2014 and 2013, are as follows:

	Millions of Yen				
At March 31, 2014	Hedged item			Fair value	
Foreign currency forward contracts: Buying U.S. \$	Forecasted transactions	¥376	¥—	¥(10)	
Interest rate swaps:					
(fixed rate payment, floating rate receipt)	Long-term debt	1,800	1,000	(11)	

	Millions of Yen			
At March 31, 2013				
Interest rate swaps:				
(fixed rate payment, floating rate receipt)	Long-term debt	¥1,800	¥1,800	¥(18)

	Thousands of U.S. Dollars			
At March 31, 2014				Fair value
Foreign currency forward contracts: Buying U.S. \$	Forecasted transactions	\$3,653	\$—	\$(97)
Interest rate swaps:				
(fixed rate payment, floating rate receipt)	Long-term debt	17,489	9,716	(107)

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.

# 20. Contingent liabilities

The Group's contingent liabilities as of March 31, 2014 are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Trade notes discounted	¥ 493	\$ 4,790
Trade notes endorsed	376	3,653
Guarantees and similar items of bank loans	1,738	16,887

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 on and after January 2010. Under the terms of the agreement, Otsuka Pharmaceutical Co., Ltd. received US\$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. As of March 31, 2014, the period of indemnity based on the aforementioned contracts has ended and there are no contingent liabilities that need to be disclosed as of March 31, 2014 (As of March 31, 2013, the contingent liability was ¥72,120 million).

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*. Judgments in favor of Otsuka Pharmaceutical Co., Ltd. were finalized for these actions in February 2013.

# 21. Comprehensive income

The components of other comprehensive income for the year ended March 31, 2014 and 2013, were as follows:

	Million	Thousands of U.S. Dollars	
	2014.3	2013.3	2014.3
Unrealized gain on available-for-sale securities:			
Gains arising during the year	¥ 8,662	¥ 10,988	\$ 84,162
Reclassification adjustments to profit or loss	(302)	147	(2,934)
Amount before income tax effect	8,360	11,135	81,228
Income tax effect	(2,892)	(3,542)	(28,099)
Total	¥ 5,468	¥ 7,593	\$ 53,129
Deferred (loss) gain on derivatives under hedge accounting:			
Gains arising during the year	¥ (28)	¥ (2)	\$ (272)
Reclassification adjustments to profit or loss	18	(14)	175
Amount before income tax effect	(10)	(16)	(97)
Income tax effect	3	5	29
Total	¥ (7)	¥ (11)	\$ (68)
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ 35,653	¥ 12,000	\$346,415
Reclassification adjustments to profit or loss	45	_	437
Amount before income tax effect	35,698	12,000	346,852
Income tax effect	_	_	_
Total	¥35,698	¥ 12,000	\$346,852
Share of other comprehensive income in associates:			
Gains arising during the year	¥ 19,168	¥ 8,969	\$186,242
Reclassification	(10)	31	(97)
Total	¥ 19,158	¥ 9,000	\$ 186,145
Total other comprehensive income	¥ 60,317	¥ 28,582	\$ 586,058

## 22. Cash flow information

(1) Details of assets and liabilities of the companies which the Company newly consolidated by acquiring their shares

### March 31, 2014

Details of assets and liabilities and price and payments for the acquisition of Claris Otsuka, Astex and one other company are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥16,146	\$156,879
Noncurrent assets	74,754	726,331
Goodwill	32,654	317,275
Current liabilities	(6,780)	(65,876)
Long-term liabilities	(10,377)	(100,826)
Minority interests	(6,860)	(66,654)
Cost of purchase of investments in subsidiaries	99,537	967,129
Cash and cash equivalent of newly consolidated companies	(4,181)	(40,624)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	¥95,356	\$926,505

### March 31, 2013

Details of assets and liabilities and price and payments for the acquisition of Valpiform SAS and one company are as follows:

	Millions of Yen
Current assets	¥ 389
Noncurrent assets	870
Goodwill	919
Current liabilities	(298)
Long-term liabilities	(11)
Cost of purchase of investments in subsidiaries	1,869
Cash and cash equivalent of newly consolidated companies	(148)
Foreign currency translation adjustments	(182)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	¥1,539

### (2) Nonmonetary transactions

There were no material nonmonetary transactions requiring disclosure for the years ended March 31, 2014 and 2013.

## 23. Net income per share

The reconciliation of the differences between basic and diluted net income per share (EPS) for the years ended March 31, 2014 and 2013, is as follows:

	Millions of Yen	Thousands of shares	Yen	U.S. Dollars
For the year ended March 31, 2014		Weighted- average shares		
Basic EPS				
Net income available to common shareholders	¥150,956	542,866	¥278.07	\$ 2.70
Effect of dilutive securities				
Warrants	(245)	_		
Stock options	_	193		
Diluted EPS				
Net income for computation	¥150,711	543,059	¥ 277.52	\$ 2.70

		Thousands of shares			
For the year ended March 31, 2013		Weighted- average shares			
Basic EPS					
Net income available to common shareholders	¥122,411	551,639	¥221.90		
Effect of dilutive securities	-				
Warrants	(152)	_			
Stock options	_	525			
Diluted EPS					
Net income for computation	¥122,259	552,164	¥221.42		

# 24. Subsequent events

### Appropriation of retained earnings

The following appropriation of retained earnings at March 31, 2014, was approved at a meeting of the Company's board of directors held on May 14, 2014:

	Millions of Yen	Thousands of U.S. Dollars
Year-end cash dividends, ¥35.0 (US\$0.34) per share	¥18,957	\$184,192





Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

## 25. Segment information

### For the years ended March 31, 2014 and 2013

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 The accounting policies of each reportable segment are consistent to those disclosed in Note 2, "Summary of Significant Accounting Policies." Income for reportable segments is based on operating income. Intersegment profit or transfers are based on market prices.

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

		Millions of Yen					
Year ended March 31, 2014	Reportable segment				Reconciliations		
Sales							
Sales to external customers	¥1,035,080	¥ 281,146	¥ 43,771	¥ 92,762	¥ 1,452,759	¥ —	¥1,452,759
Intersegment sales and transfers	_	5,987	155	37,578	43,720	(43,720)	_
Total	1,035,080	287,133	43,926	130,340	1,496,479	(43,720)	1,452,759
Segment profit (loss)	212,755	25,363	(2,166)	7,235	243,187	(44,484)	198,703
Segment assets	802,804	216,807	141,716	147,439	1,308,766	719,634	2,028,400
Other:							
Depreciation	23,775	11,426	1,443	4,394	41,038	4,994	46,032
Amortization of goodwill	1,707	1,760	118	129	3,714	_	3,714
Investment in equity-method affiliated companies	28,610	11,987	115,333	17,455	173,385	_	173,385
Increase in property, plant, and equipment and intangible assets	154,514	10,144	2,912	4,359	171,929	7,055	178,984

	Millions of Yen						
Year ended March 31, 2013	Reportable segment				Reconciliations		
Sales							
Sales to external customers	¥850,862	¥246,929	¥ 45,237	¥ 75,027	¥ 1,218,055	¥ —	¥1,218,055
Intersegment sales and transfers	_	4,844	1,652	36,637	43,133	(43,133)	_
Total	850,862	251,773	46,889	111,664	1,261,188	(43,133)	1,218,055
Segment profit (loss)	187,853	21,367	(2,446)	3,919	210,693	(41,033)	169,660
Segment assets	589,861	207,679	133,677	124,191	1,055,408	723,800	1,779,208
Other:							
Depreciation	18,995	10,222	1,756	4,494	35,467	5,148	40,615
Amortization of goodwill	2,807	1,851	63	127	4,848	_	4,848
Investment in equity-method affiliated companies	21,457	10,121	104,964	10,914	147,456	_	147,456
Increase in property, plant, and equipment and intangible assets	37,951	14,939	2,735	3,973	59,598	3,658	63,256

Year ended March 31, 2014	Reportable segment						
						Reconciliations	
Sales							
Sales to external customers	\$10,057,132	\$ 2,731,695	\$ 425,291	\$ 901,302	\$14,115,420	\$ —	\$14,115,420
Intersegment sales and transfers	_	58,171	1,507	365,118	424,796	(424,796)	_
Total	10,057,132	2,789,866	426,798	1,266,420	14,540,216	(424,796)	14,115,420
Segment profit (loss)	2,067,188	246,434	(21,045)	70,297	2,362,874	(432,219)	1,930,655
Segment assets	7,800,272	2,106,558	1,376,953	1,432,560	12,716,343	6,992,169	19,708,512
Other:							
Depreciation	231,005	111,018	14,021	42,693	398,737	48,523	447,260
Amortization of goodwill	16,586	17,101	1,147	1,252	36,086	_	36,086
Investment in equity-method affiliated companies	277,983	116,469	1,120,608	169,598	1,684,658	_	1,684,658
Increase in property, plant, and equipment and intangible assets	1,501,302	98,562	28,294	42,353	1,670,511	68,548	1,739,059

#### Notes:

- 2) Adjustments to segment assets of ¥719,634 million (US\$6,992,169 thousand) include intersegment eliminations of ¥7,466 million (US\$72,542 thousand) and corporate assets of ¥727,100 million (US\$7,064,710 thousand) for the year ended March 31, 2014. Adjustments to segment assets of ¥723,800 million include intersegment eliminations of ¥7,370 million and corporate assets of ¥731,170 million for the year ended March 31, 2013. 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 statement of income.

### 4. Information about products and services

2014.3	Millions of Yen			
2014.5			Total	
Sales to external customers	¥575,732	¥877,027	¥1,452,759	

2013.3	Millions of Yen			
2015.5			Total	
Sales to external customers	¥438,514	¥779,541	¥1,218,055	

2014.2				
2014.3			Total	
Sales to external customers	\$5,593,976	\$8,521,444	\$14,115,420	

### 5. Information about geographical areas

### (1) Sales

Millions of Yen					
2014.3					
Japan					
¥628,317	¥599,559	¥224,883	¥1,452,759		

Millions of Yen					
2013.3					
Japan			Total		
¥595,308	¥445,678	¥177,069	¥1,218,055		

Thousands of U.S. Dollars					
2014.3					
Japan					
\$6,104,907	\$5,825,486	\$2,185,027	\$14,115,420		

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

### (2) Property, plant, and equipment

Millions of Yen					
2014.3					
Japan					
¥217,048	¥32,193	¥65,944	¥315,185		

Millions of Yen					
2013.3					
Japan					
¥211,888	¥23,438	¥40,641	¥275,967		

Thousands of U.S. Dollars					
2014.3					
Japan					
\$2,108,900	\$312,796	\$640,731	\$3,062,427		

In the previous fiscal year, "North America" was included in "Other," however, from the current year, it is presented separately since property, plant and equipment of North America exceed 10% of that of the consolidated balance sheet as of March 31, 2014. To reflect this change in method of presentation, item "5. Information about geographical areas (2) Property, plant, and equipment" for the previous fiscal year is reclassified. As a result, the ¥64,079 million that was previously presented as "Other" is reclassified as ¥23,438 million in "North America" and ¥40,641 million in "Other."

### 6. Information about major customers

2014.2	Millions of Yen			
2014.3		Segment		
McKesson Corporation	¥177,713	Pharmaceuticals		
Cardinal Health Inc.	161,699	Pharmaceuticals		

2012.2	Millions of Yen			
2013.3				
McKesson Corporation	¥133,693	Pharmaceuticals		
Cardinal Health Inc.	128,931	Pharmaceuticals		

2014.2	Thousands of U.S. Dollars			
2014.3				
McKesson Corporation	\$1,726,710	Pharmaceuticals		
Cardinal Health Inc.	1,571,113	Pharmaceuticals		

<sup>1)</sup> Adjustments to segment profit of ¥44,484 million (US\$432,219 thousand) include intersegment eliminations of ¥758 million (US\$7,365 thousand) and unallocated corporate expenses of ¥45,242 million (US\$439,584 thousand) for the year ended March 31, 2014. Adjustments to segment profit of ¥41,033 million include intersegment eliminations of ¥639 million and unallocated corporate expenses of ¥41,672 million for the year ended March 31, 2013. Corporate expenses include costs associated with headquarter functions.



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd. and its Consolidated Subsidiaries

### 7. Information about impairment losses on fixed assets

	Millions of Yen					
2014.3						Total
Impairment losses	¥ 33	¥ 2,844	¥ 459	¥ 8	¥ 55	¥ 3,399

	Millions of Yen					
2013.3						Total
Impairment losses	¥ 1,131	¥ 954	¥ 214	¥201	¥ 71	¥ 2,571

2014.3	Thousands of U.S. Dollars					
						Total
Impairment losses	\$ 321	\$27,633	\$ 4,460	\$ 78	\$534	\$ 33,026

## 8. Information about amortization of goodwill and goodwill balance

	Millions of Yen					
2014.3						Total
Amortization of goodwill	¥ 1,707	¥ 1,760	¥ 118	¥ 129	¥ —	¥ 3,714
Goodwill at March 31, 2014	41,469	26,669	478	1,979	_	70,595

	Millions of Yen					
2013.3						Total
Amortization of goodwill	¥ 2,807	¥ 1,851	¥ 63	¥ 127	¥ —	¥ 4,848
Goodwill at March 31, 2014	7,102	28,085	538	2,063	_	37,788

	Thousands of U.S. Dollars					
2014.3						Total
Amortization of goodwill	\$ 16,586	\$ 17,101	\$ 1,147	\$ 1,252	\$ <i>—</i>	\$ 36,086
Goodwill at March 31, 2014	402,925	259,124	4,644	19,228	_	685,921

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

2014.3	Millions of Yen						
						Total	
Amortization of negative goodwill	¥ 2,208	¥ —	¥ —	¥ 440	¥ —	¥ 2,648	
Negative goodwill at March 31, 2014	19,456	_	_	2,085	_	21,541	

2013.3	Millions of Yen						
						Total	
Amortization of negative goodwill	¥ 2,208	¥ —	¥ —	¥ 256	¥ —	¥ 2,464	
Negative goodwill at March 31, 2013	21,663	_		2,342	_	24,005	

2014.3	Thousands of U.S. Dollars						
						Total	
Amortization of negative goodwill	\$ 21,454	\$ <i>—</i>	\$ <i>—</i>	\$ 4,275	\$ <i>—</i>	\$ 25,729	
Negative goodwill at March 31, 2014	189,040	_	_	20,258	_	209,298	

## 10. Information about gain on negative goodwill

In the fiscal years ended March 31, 2014 and 2013, there was no gain on negative goodwill.



# Deloitte.

Deloitte Touche Tohmatsu LLC Shinagawa Intercity 2-15-3, Konan Minato-ku, Tokyo 108-6221 Japan

Tel:+81 (3) 6720 8200 Fax:+81 (3) 6720 8205 www.deloitte.com/ip

#### 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 its consolidated subsidiaries as of March 31, 2014, 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 accordance 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 misstatement, 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 accordance 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 its consolidated subsidiaries as of March 31, 2014, and the consolidated results of their operations and their cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

### Convenience Translation

Deloise Touche Tohnoten LLC

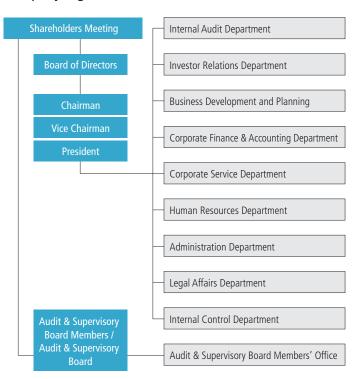
Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in accordance with the basis stated in Note 1 to the consolidated financial statements. Such U.S. dollar amounts are presented solely for the convenience of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

June 27, 2014

Member of
Deloitte Touche Tohmatsu Limited



## Company organization (as of June 30, 2014)



### **Board members**

Chairman and Representative Director Akihiko Otsuka

Vice Chairman and Representative Director Ichiro Otsuka

President and Representative Director, CEO

Tatsuo Higuchi

**Senior Managing Director** Atsumasa Makise

**Managing Director** Yoshiro Matsuo

**Executive Directors** Sadanobu Tobe Tatsuro Watanabe

**Outside Directors** Yasuyuki Hirotomi Juichi Kawaguchi Tadaaki Kounose

Standing Audit & Supervisory Board Member Takaharu Imai

Audit & Supervisory Board Member Akihito Nakai

Outside Audit & **Supervisory Board Members** Norikazu Yahagi Hiroshi Sugawara

### Corporate profile (as of March 31, 2014)

**Company Name** Otsuka Holdings Co., Ltd.

**Established** July 8, 2008 ¥81.69 billion Capital

2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan **Head Office** 

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

+81-3-6717-1410 (switchboard) Telephone Number of employees 75 (Consolidated: 28,288)

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

pharmaceutical industry, nutraceutical industry, consumer products and other areas.

URL http://www.otsuka.com/en/

## Website information

IR and SR information available on Otsuka Holdings website.

Otsuka Holdings

Investor Relations

http://www.otsuka.com/en/ http://www.otsuka.com/en/ir/

Social Responsibility

http://otsuka.csrportal.jp/en/





Number of shares authorized 1,600,000,000 Number of shares issued 557,835,617 Number of shareholders 53,188

# Principal shareholders

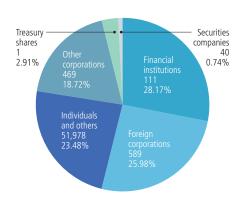
Name	Number of shares held (Thousand)	Shareholding ratio (%)
The Nomura Trust and Banking Co., Ltd. Otsuka Founders Shareholding Fund Trust Account	62,936	11.61
Otsuka Estate Limited	25,511	4.71
Otsuka Group Employee Shareholding Fund	18,964	3.50
The Master Trust Bank of Japan, Ltd. (trust account)	15,100	2.78
Japan Trustee Services Bank, Ltd. (trust account)	14,763	2.72
The Awa Bank, Ltd.	10,970	2.02
GOLDMAN, SACHS & CO. REG	7,824	1.44
Otsuka Asset Co., Ltd.	7,720	1.42
TOHO HOLDINGS CO., LTD.	7,270	1.34
Resona Bank, Limited.	5,568	1.02

#### Notes

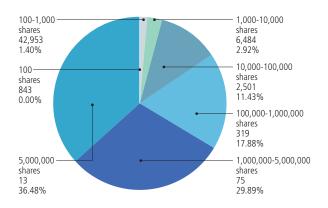
- 1. Number of shares held is rounded down to the nearest thousand.
- 2. The company holds treasury stock(16,211,155 shares) but is excluded from the principal shareholders listed above.
- 3. Shareholding ratio is calculated after treasury stock is deducted.

# Stock distribution

### Distribution of Shares by Type of Shareholder



### Distribution of Shares by Number of Shares Owned





This annual report summarizes the operating and financial results of Otsuka Holdings Co., Ltd. and its subsidiaries and affiliates for fiscal 2013 (April 1, 2013 to March 31, 2014). It also includes information regarding selected material events which occurred between April 1, 2014 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, promoting or medical advice.







