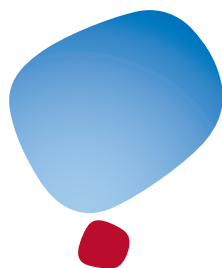


# ANNUAL REPORT 2015

For the year ended December 31, 2015



Otsuka

Otsuka-people creating new products  
for better health worldwide

Otsuka Holdings Co., Ltd.

# Otsuka-people creating new products for better health worldwide

These words embody our commitment to:

Creating innovative products

Improving human health

Contributing to the lives of people worldwide

In keeping with this corporate philosophy and the Otsuka mottoes of Jissho (Proof through Execution) and Sozosei (Creativity), the Otsuka Group strives to utilize its unique assets and skills to develop differentiated scientific solutions which contribute to the lives of people worldwide in the form of innovative and creative products ranging from pharmaceuticals to consumer products. We are striving to cultivate a culture and a dynamic corporate climate reflecting our vision as a healthcare company.

Consistent with this approach, we are dedicated to achieving global sustainability, to our relationships with local communities and to the protection of the natural environment.



### Monuments embodying the Otsuka Group Philosophy Giant Tomato Trees / Bent Giant Cedar / Floating Stone

These three monuments embody the Otsuka Group philosophy, reminding all who visit the birthplace of the Otsuka Group in Tokushima of the importance of being creative and open-minded to new ideas.

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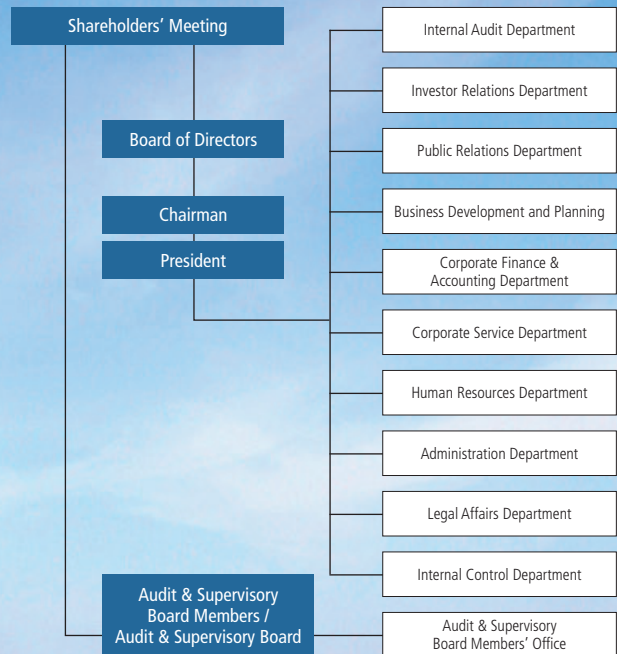
# Corporate Information

Otsuka Holdings was established on July 8, 2008 as a holding company for the Otsuka Group to improve overall Group corporate value. Otsuka Holdings supports the sustainable growth of Group companies, maximizes the Group's synergies by integrating management resources, increases management efficiency, and empowers employees and organizations.

## Corporate profile (as of December 31, 2015)

<b>Company Name</b>	Otsuka Holdings Co., Ltd.
<b>Established</b>	July 8, 2008
<b>Capital</b>	¥81.69 billion
<b>Head Office</b>	2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan
<b>Tokyo Headquarters</b>	Shinagawa Grand Central Tower, 2-16-4 Konan, Minato-ku, Tokyo 108-8241, Japan
<b>Telephone</b>	+81-3-6717-1410 (switchboard)
<b>Number of employees</b>	78 (Consolidated: 30,638)
<b>Business description</b>	Control, management and related activities with respect to the Company's subsidiaries and affiliates active in the pharmaceutical industry, nutraceutical industry, consumer products and other areas.
<b>URL</b>	<a href="http://www.otsuka.com/en/">http://www.otsuka.com/en/</a>

## Company organization (as of April 30, 2016)



**p.03** Directors  
Audit & Supervisory  
Board Members

**p.04** Business Model

**p.10** Message from the President

**p.48** Corporate Governance

## Directors



Front row, from left: Atsumasa Makise, Ichiro Otsuka, Tatsuo Higuchi, Yoshiro Matsuo  
 Back row, from left: Tadaaki Kounose, Tatsuro Watanabe, Sadanobu Tobe, Yasuyuki Hirotoomi, Yukio Matsutani

**Chairman and  
 Representative Director**

Ichiro Otsuka

**President and  
 Representative Director, CEO**

Tatsuo Higuchi

**Senior Managing  
 Directors**

Atsumasa Makise  
 Yoshiro Matsuo

**Executive  
 Directors**

Sadanobu Tobe  
 Tatsuro Watanabe

**Outside  
 Directors**

Yasuyuki Hirotoomi  
 Tadaaki Kounose  
 Yukio Matsutani

## Audit & Supervisory Board Members



From left: Hiroshi Sugawara, Takaharu Imai, Norikazu Yahagi, Yoko Wachi

**Standing Audit &  
 Supervisory Board Member**

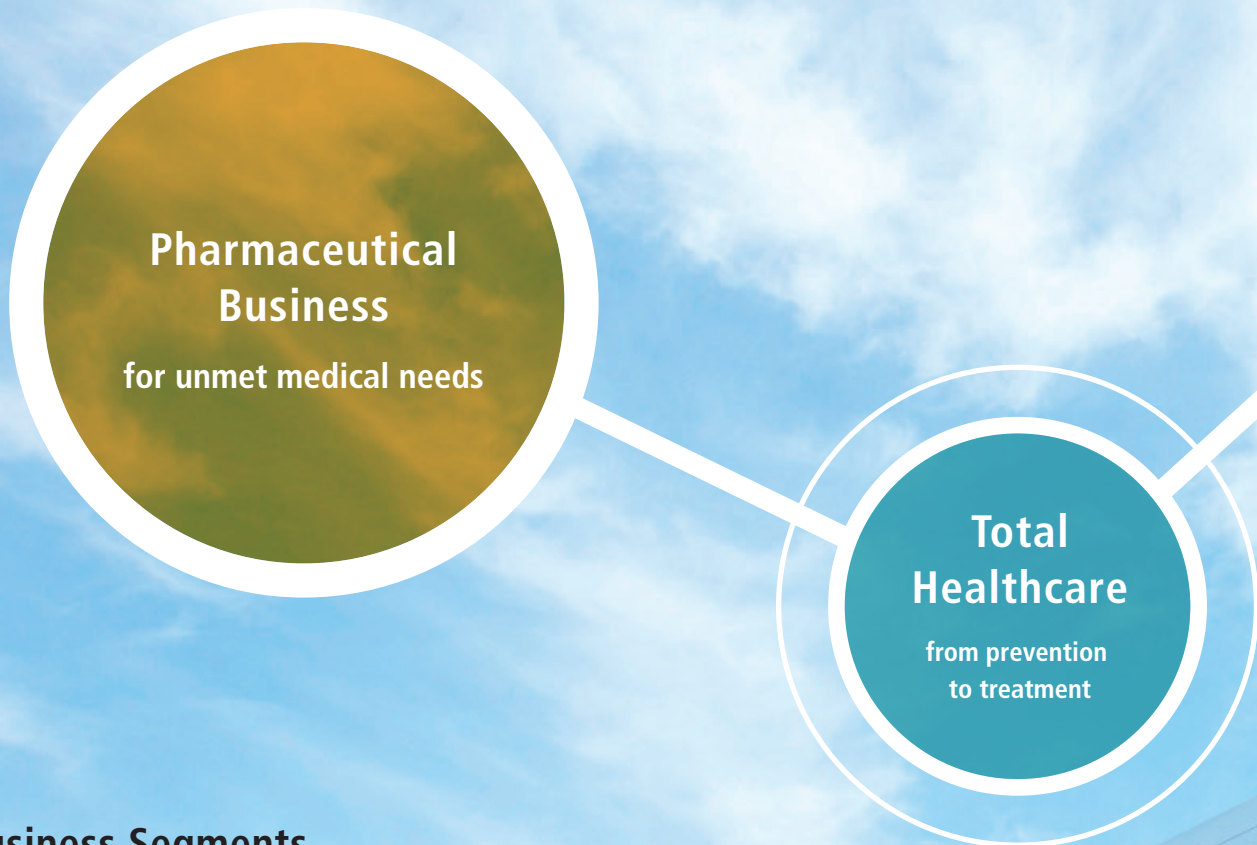
Takaharu Imai

**Outside Audit &  
 Supervisory Board Members**

Norikazu Yahagi  
 Hiroshi Sugawara  
 Yoko Wachi

## Business Model

The Otsuka Group operates a wide range of businesses to contribute to the health of people all around the world. Taking a comprehensive view of healthcare, the Group focuses on the pharmaceutical business, which provides comprehensive health support from diagnosis to treatment of diseases, and the nutraceutical business, which helps to maintain and promote people's health.



## Business Segments

### Pharmaceutical business

- Therapeutic drugs
- Clinical nutrition
- Diagnostics
- Medical devices

The Otsuka Group's pharmaceutical business focuses on the core areas of the central nervous system and oncology. Furthermore, the Group is engaged in a wide range of fields and businesses, including the cardiovascular system, gastroenterology, ophthalmology, clinical nutrition, and diagnostics and medical device businesses.

### Nutraceutical business

- Functional beverages and foods
- Cosmetics
- OTC products, Quasi-drugs

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

### Consumer products business

- Beverages
- Foods
- Alcoholic beverages

The Otsuka Group's consumer products business focuses on delivering familiar food and beverages that are delicious, safe, reassuring, and healthy.

### Other business

- Chemicals
- Distribution
- Packaging
- Electronic equipment

The Otsuka Group's other business operates multiple businesses such as chemicals, transportation, warehousing, and electronic equipment.

# Nutraceutical Business

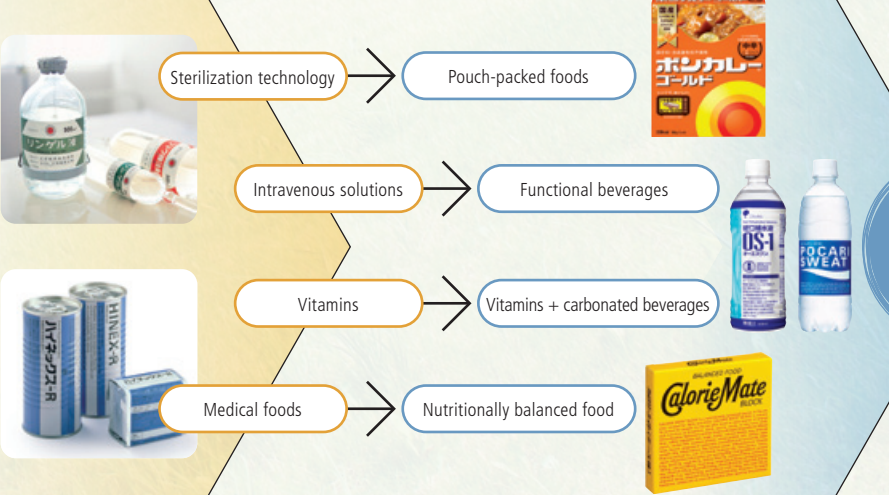
for yet-to-be-imagined needs



## Innovative Products Developed for the Pharmaceutical Business

The Otsuka Group has developed a wide range of products utilizing its experience and expertise in clinical nutrition—the bedrock of its business since the beginning—and has harnessed this spirit of innovation to create new markets. Many of its products have become long sellers with influential brand strength.

Ideas from our pharmaceutical business

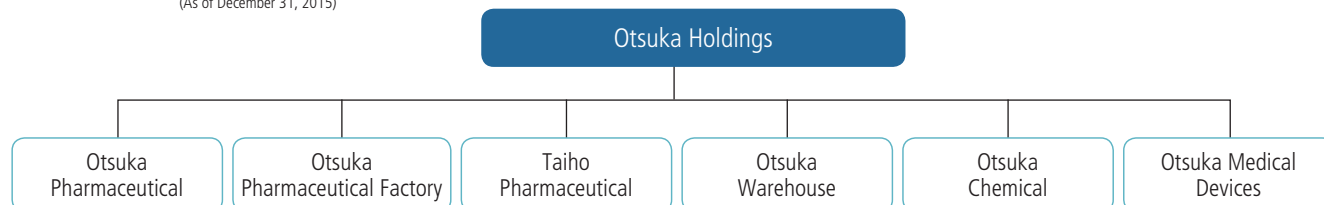


# Group Structure & Overview of Main Operating Companies

Based on the corporate philosophy of “Otsuka-people creating new products for better health worldwide,” Otsuka Holdings aims to lead a global value-creating group that is dedicated to contributing to a healthier and more prosperous life for people the world over.

## Group structure

(As of December 31, 2015)



Otsuka Pharmaceutical Co., Ltd.

Established in 1964, Otsuka Pharmaceutical operates a pharmaceutical business and a nutraceutical business, aiming to care for people’s overall health not only by treating illness, but also by sustaining day-to-day well-being as a total healthcare company. Its products are available in more than 80 countries worldwide. In a continuing effort to address unmet medical needs, Otsuka Pharmaceutical contributes to people’s health worldwide by developing unique and innovative products and building new category markets.



Otsuka Pharmaceutical Factory, Inc.

Otsuka Pharmaceutical Factory, Inc., founded in 1935 as the successor to Otsuka Seiyaku Kogyo-bu, which was established in 1921, is a Group company that creates innovative products to fulfill a range of needs. These include intravenous solutions as well as medical foods such as oral rehydration drinks. The company also utilizes the technology it has built up thus far to manufacture products on commission. Its products reach markets beyond Japan’s shores, particularly in Asia. Otsuka Pharmaceutical Factory will continue to deliver a stable supply of safe, high-quality products to patients and healthcare professionals.



Taiho Pharmaceutical Co., Ltd.

Established in 1963, Taiho Pharmaceutical is a pioneer in the field of oral anti-cancer agents and is known in Japan as “Taiho, the anticancer drug maker.” The company has also been developing unique and novel drugs in the fields of allergy/immunology and urology. In the consumer healthcare business, 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 Warehouse Co., Ltd.

Otsuka Warehouse was established in 1961. The company supports the storage and distribution of Group companies’ products, operating a shared platform specializing in the Group’s pharmaceutical products, food and beverages and everyday goods. Due to its outstanding logistics offerings, 55% of Otsuka Warehouses sales now come from outside the Otsuka Group. In recent years, the company has also developed a logistics system that anyone can manage by implementing a strategy for leveraging data and IT.



Otsuka Chemical Co., Ltd.

Otsuka Chemical has been developing a range of businesses since 1950. These include operations in hydrazine-related business such as foaming agents, a fine chemicals business handling materials such as pharmaceutical intermediates, and a materials business that supplies titanate and engineering plastics compounds. Its company 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 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.

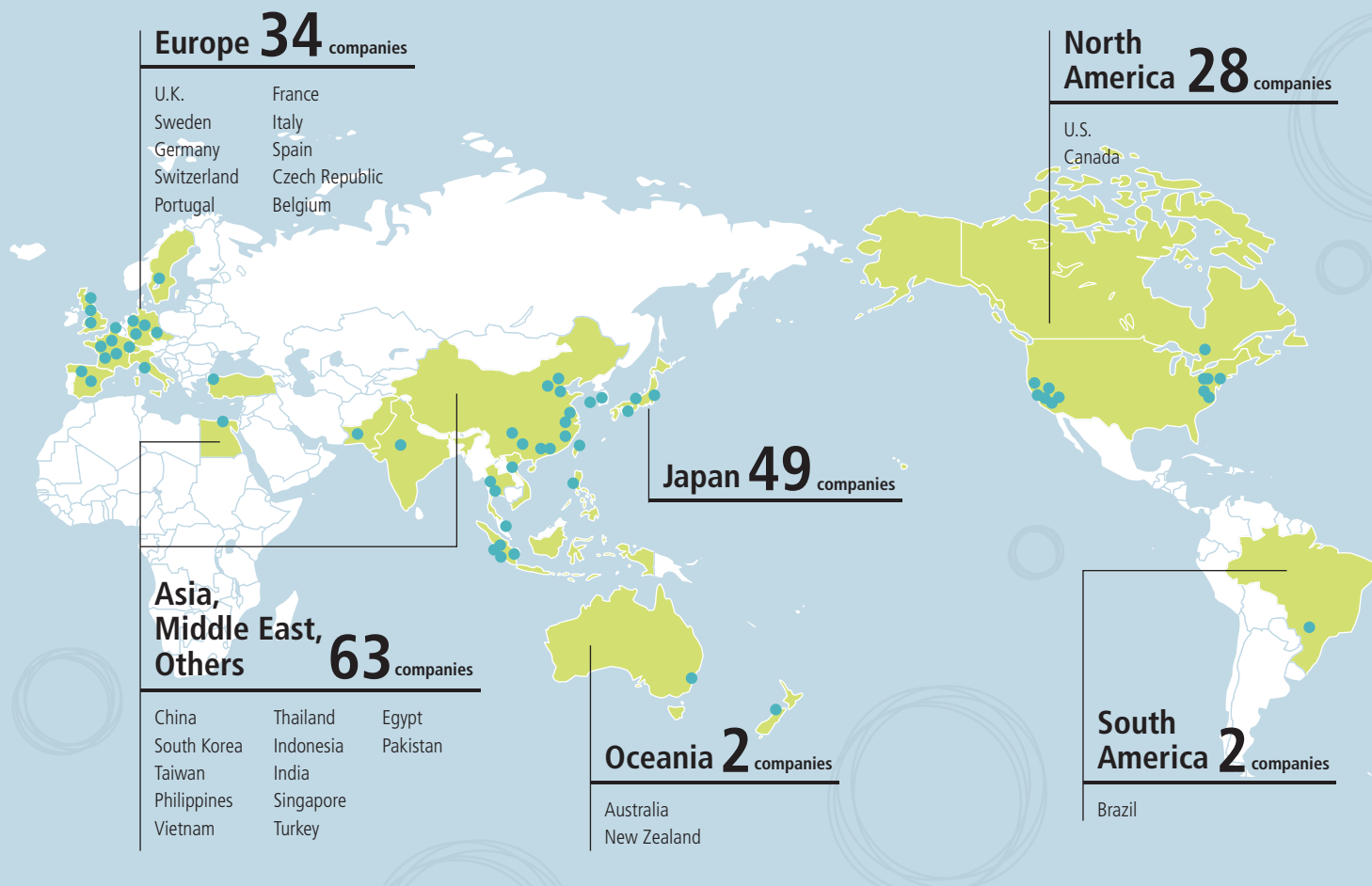
Otsuka Medical Devices was established in 2011. The company operates its business globally, overseeing the Otsuka Group’s medical device businesses. One such enterprise is JIMRO, which manufactures and sells *Adacolumn*, an apheresis device for granulocyte adsorption in inflammatory bowel disease. Other businesses include Liliun Otsuka, which manufactures and markets bladder urinary volume measurement devices, Achieva Medical and Microport Scientific, both located in Shanghai, China, and Era Endoscopy based in Pisa, Italy. Otsuka Medical Devices is aiming to find solutions for treating drug-refractory patients and intractable diseases through advances in medical devices.



# Global Network

The Otsuka Group consists of 178 companies\* worldwide operating with the common theme of "health." The Group comprises 112 consolidated subsidiaries and 16 affiliates accounted for by the equity method.

\* Including unconsolidated subsidiaries (as of December 31, 2015)

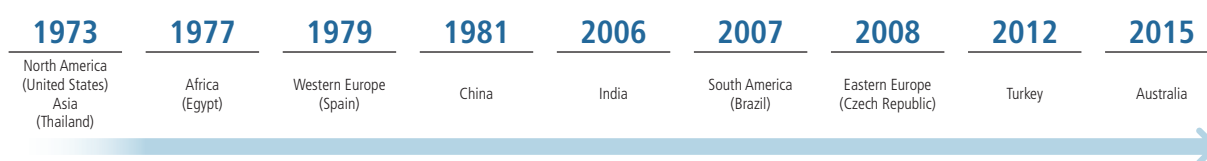


## Number of operations and employees of the Otsuka Group

	Companies	Factories	Research Institutes	Employees
<b>Worldwide</b>	<b>178</b>	<b>194</b>	<b>48</b>	<b>Approx. 47,000</b>
<b>Japan</b>	49	54	25	Approx. 18,000
<b>Overseas</b>	129	140	23	Approx. 29,000

\* Including unconsolidated subsidiaries

## History of Otsuka's global business expansion



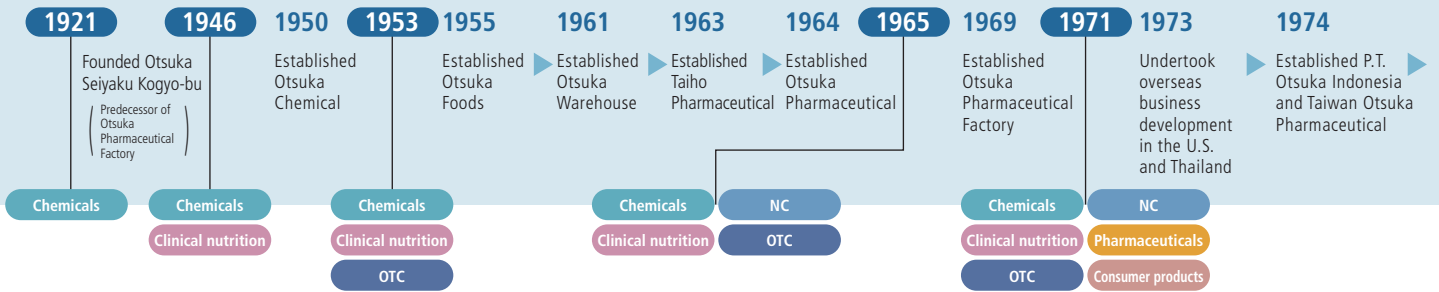
# History

## Foundation phase

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

## Growth phase

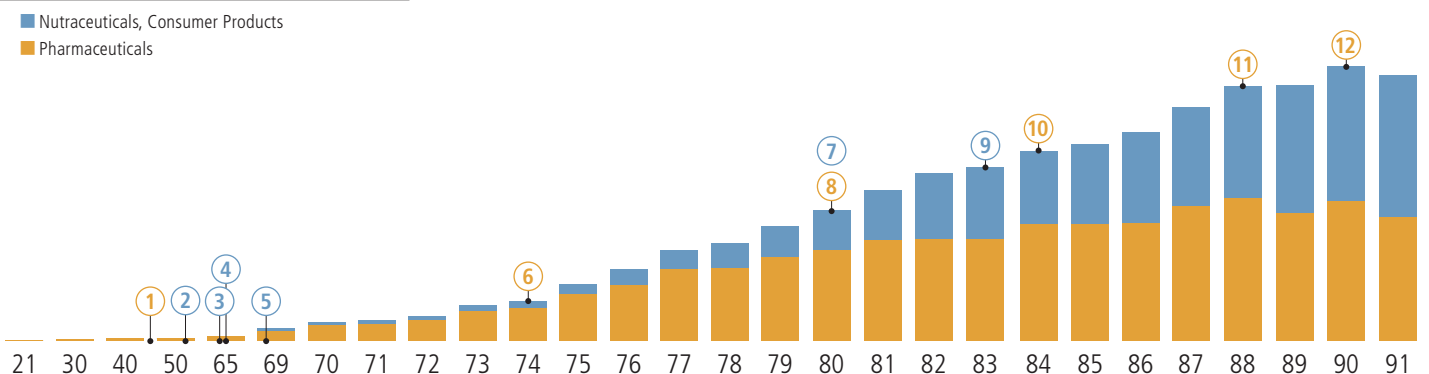
Opened the Tokushima Research Institute with the aim of in-house drug development. Numerous nutraceutical products opened up new markets, diversifying the Group's business



## History of product development



## Otsuka Group Sales Trend



## History of M&A and alliances

### 1980~

- 1989** ● Pharmavite joined the Otsuka Group
- 1990** ● Crystal Geysir\*<sup>1</sup> joined the Otsuka Group
- 1999** ● Co-development and co-commercialization agreement for ABILIFY with BMS\*<sup>2</sup> (U.S. and EU)

### 2000~

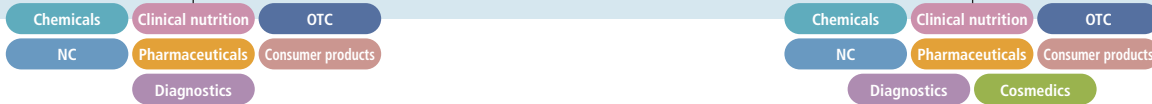
- 2004** ● Equity participation in MicroPort Medical
- 2005** ● Equity participation in VV Food & Beverage and expanded SOYJOY business in China
- 2008** ● Equity participation in major mineral water company, ALMA
- 2009** ● Co-development and co-commercialization agreement for Sprycel and Ixempra with BMS (Global)
- N&S\*<sup>3</sup> joined the Otsuka Group

**International business development phase**

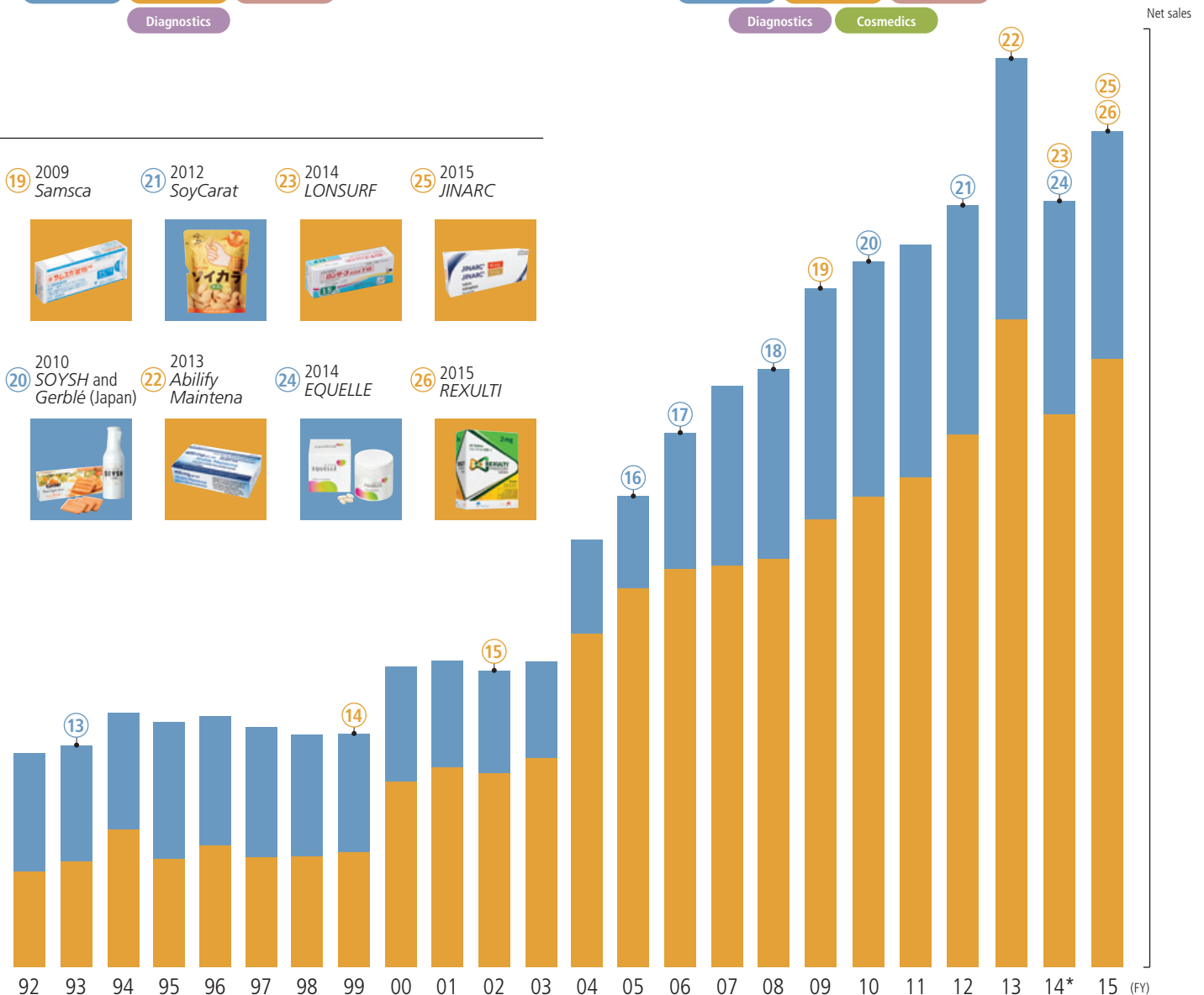
Started aggressive global expansion

**Expansion phase**

Pursuing further global growth



NC: Nutraceuticals



\* Consolidated financial report for the transitional fiscal 2014 period represents the results for the nine-month period from April 1 to December 31, 2014.

**2010~**

- 2011** ● Alliance agreement with Lundbeck in the central nervous system (CNS) field (Global)
- 2012** ● Valpiform joined the Otsuka Group
- 2013** ● Astex joined the Otsuka Group  
● Equity participation in Claris Otsuka
- 2014** ● Ateco Pharma Egypt joined the Otsuka Group  
● Jasmine joined the Otsuka Group  
● Higashiyama Film joined the Otsuka Group  
● FoodState joined the Otsuka Group
- 2015** ● Avanir joined the Otsuka Group  
● License agreement with Servier for development and commercialization of LONSURF (Europe and other countries)  
● BIOCENTURY joined the Otsuka Group

\*1: Crystal Geyser Water Company  
\*2: Bristol-Myers Squibb Company  
\*3: Nutrition & Santé

### For Sustainable Growth beyond 2018



The Otsuka Holdings Second Medium-Term Management Plan, which runs through the end of fiscal 2018, places strategic focus on “maximizing product value” in our pharmaceutical business and “accelerating global expansion and reviewing business assets” in our nutraceutical business. The plan also puts the Group on track for growth by diversifying our profit structure, while taking steps to strengthen our business structure.

Our goal is sustainable growth based on a long-term vision. We must not only concern ourselves with short-term outcomes, but also look for answers to real questions about what patients and consumers want and then create innovative products that are competitive. The Otsuka Group’s unique assets of Jissho (proof through execution) and Sozosei (creativity) are built into our corporate culture, and as we move quickly toward our goals, we will work to fully integrate this culture into all aspects of our operations, from research and development to production and marketing.

In order to ensure corporate transparency and fairness and to increase corporate value over the long term, Otsuka Holdings established Corporate Governance Guidelines in November 2015, setting out the basic policy for the Otsuka Group’s governance structure. We take seriously our mission of contributing to people’s health and operate our businesses ethically and with integrity to earn the trust of all of our stakeholders and to meet the needs of society.

# Laying Foundations for Sustainable Growth



## The Otsuka Group's Goals *To Become an Indispensable Company*

The Otsuka Group runs its business activities with the aim of providing people all over the world with innovative products and contributing to their health. All of its activities are motivated by its corporate philosophy, "Otsuka-people creating new products for better health worldwide."

As a group of companies committed to providing total healthcare, Otsuka aims to become an indispensable contributor to sustainable social development and people's health worldwide.

## Role of the Second Medium-Term Management Plan *Five-Year Plan to Diversify Revenue Structure*

The Otsuka Group's Second Medium-Term Management Plan, slated to end in fiscal 2018, is built around the Group's corporate philosophy. Specific initiatives are currently underway.

The Second Medium-Term Management Plan is designed to build a more diversified business portfolio and promote sustainable growth by pursuing ongoing investment and structural reform. The Group is working to expand business opportunities through a seamlessly organic integration of people, technology and products, aiming to provide total healthcare in keeping with its corporate philosophy.

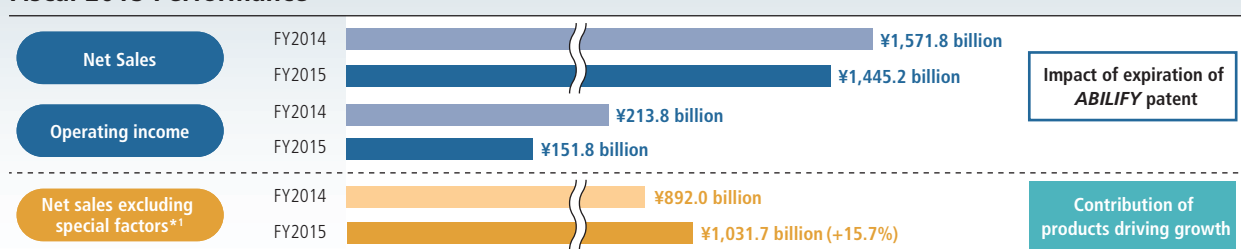
## Progress in FY 2015 *Effect of Steps to Diversify Business and Achieve Sustainable Growth*

In fiscal 2015, the second year of the Second Medium-Term Management Plan, the patent for the atypical antipsychotic agent **ABILIFY**—a product that has driven the Group's growth—expired in the U.S. As a result, net sales fell compared to the previous year to ¥1,445.2 billion and operating income dropped to ¥151.8 billion.

Offsetting this, measures are progressing in line with the Second Medium-Term Management Plan. Sales of the key growth drivers are increasing steadily. In the pharmaceutical business, global products and new drugs in Japan are achieving steady growth. These products include **Abilify Maintena**, an extended-release injectable suspension of **ABILIFY**, and **Samsca/JINARC**, which is indicated as an aquaretic and is also the world's first therapeutic drug for autosomal dominant polycystic kidney disease (ADPKD). Growth in the nutraceuticals business is being driven by **Pocari Sweat** in Japan and China, nutrition foods in Europe, and nutritional supplements in the U.S., yielding higher sales and profit.

As these examples illustrate, Otsuka is delivering steady progress with its line-up of products positioned as growth drivers. As a result, net sales, excluding special factors such as **ABILIFY**'s sales, rose 15.7% over the previous year, indicating that the Group's efforts to diversify its business portfolio and achieve sustainable growth are seeing success.

### Fiscal 2015 Performance



\*1 Net sales excluding **ABILIFY** and milestone/upfront revenue

\* As a result of the adoption of a new fiscal year end, the fiscal year ended December 31, 2014 was an irregular nine-month period. For reference, we have included consolidated profit/loss figures (not audited) for all consolidated companies for the period from January 1, 2014 to December 31, 2014.

# Progress in Pharmaceutical Business

## Global New Drugs Are Growing Steadily

Strengthening the Otsuka Group's franchise in its core fields of the central nervous system (CNS) and oncology forms the strategic backbone of the Group's Second Medium-Term Management Plan. The Group will continue to take on this challenge, focusing on new products that will be major growth drivers.

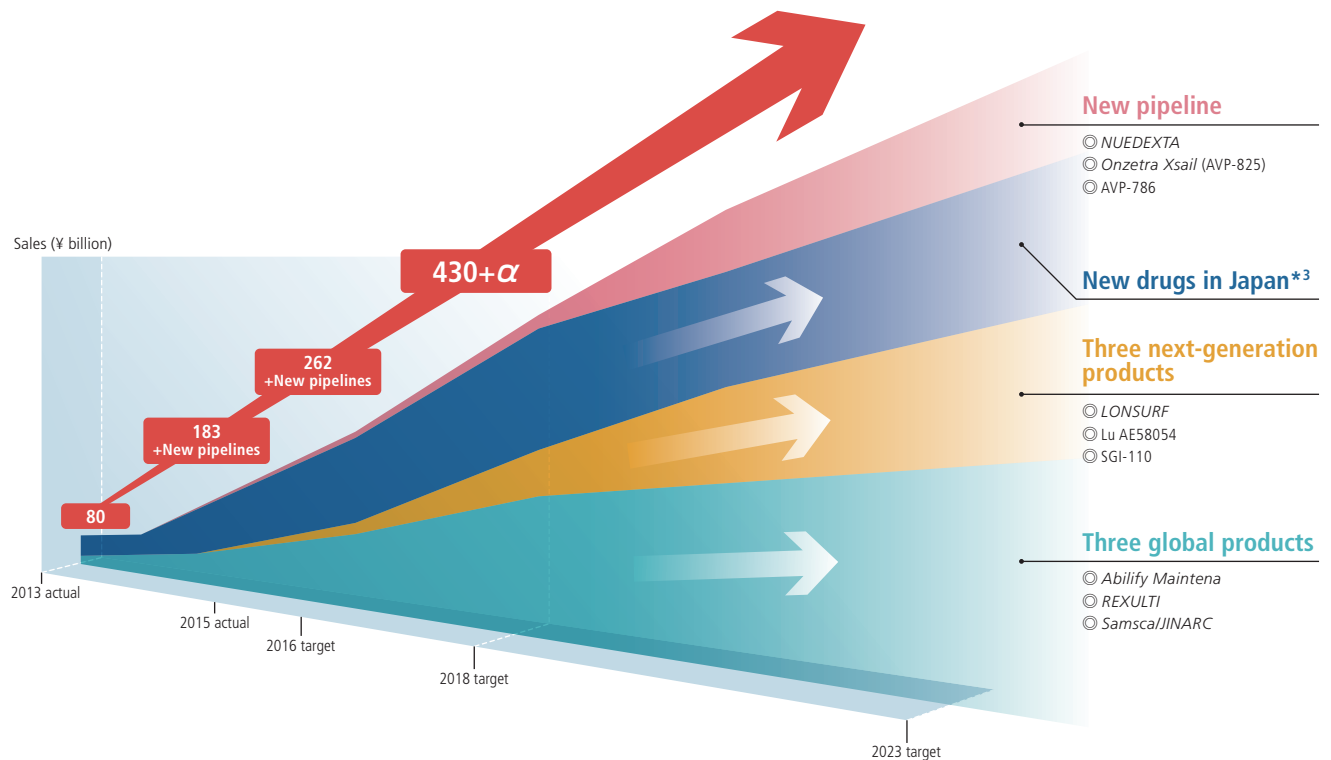
**Abilify Maintena**, an extended-release injectable suspension of **ABILIFY**, has been released in Japan, the U.S. and Europe, and its growth is now picking up globally. At present, Phase III clinical trials are underway to test its efficacy and safety in patients with bipolar disorder, as the Group pursues life cycle management of the product to ensure further growth.

Inheriting the impressive profile of **ABILIFY**, the new antipsychotic **REXULTI (brexpiprazole)** is intended to overcome unresolved issues related to psychiatric diseases. This drug was approved by the U.S. Food and Drug Administration (FDA) in July 2015 as an adjunctive therapy for the treatment of adults with major depressive disorder (MDD) and as a treatment for adults with schizophrenia. Phase III clinical trials are in progress for the use of **REXULTI** to treat agitation in patients with dementia of the Alzheimer's type, an indication for which **ABILIFY** and other atypical antipsychotic agents were not approved.

**Samsca/JINARC**, a vasopressin receptor 2 antagonist, is the world's first therapeutic agent for ADPKD, a disease for which drug treatment was previously unavailable. After receiving approval in Japan, it was also approved in Canada and Europe. In addition to growth as an aquaretic agent, its contribution as an ADPKD treatment will further optimize product value in the future.

**LONSURF**, a new anticancer drug, has been approved in Japan and the U.S. as a treatment for colorectal cancer. Going forward, the Group will accelerate the U.S. expansion of its oncology business by strengthening its in-house marketing platform. Following the U.S., **LONSURF** was also approved in Europe. In addition, Taiho Pharmaceutical entered into a licensing agreement with Servier on its development and marketing rights in Europe and other countries (excluding North America and Asia). The two companies will carry out global clinical trials to expand indications, for early maximization of the drug's value globally. At present, a Phase III clinical trial for the efficacy and safety of **LONSURF** in patients with gastric cancer is ongoing.

The Otsuka Group is making steady progress in gaining approvals of new drugs, approvals of additional indications for existing products, and expanding its market reach in line with the Second Medium-Term Management Plan. Net sales of the new drugs totaled ¥183.0 billion\*<sup>2</sup> in fiscal 2015, far exceeding the target set when the Second Medium-Term Management Plan was developed. The Group will continue its efforts with the aim of achieving net sales of new drugs exceeding the ¥430 billion\*<sup>2</sup> targeted for fiscal 2018, the last year of the plan.



\*<sup>2</sup> Total sales of the three global products (*Abilify Maintena*, *REXULTI*, and *Samsca/JINARC*), the three next-generation products (*LONSURF*, Lu AE58054, and SGI-110) and new drugs in Japan

\*<sup>3</sup> Products newly launched or to be launched in Japan between 2009 and 2018, excluding the three global products and the three next-generation products.

## Acquisition of Avanir Pharmaceuticals Offers Further Growth Opportunities

U.S.-based bio-venture company Avanir Pharmaceuticals, Inc. ("Avanir") which is particularly strong in neurological diseases, joined the Otsuka Group in January 2015.

Avanir Pharmaceuticals succeeded in developing and commercializing **NUDEXTA**, the world's first and only treatment for the neurological disease pseudobulbar affect (PBA). Sales have grown steadily as the Group has educated patients and prescribers about the disease and demonstrated with clinical trial data its efficacy for each underlying neurological condition. PBA is a neurological disorder characterized by involuntary outbursts of crying or laughter due to damage in the areas of the brain that control normal expression of emotion. **NUDEXTA** has been welcomed by the many patients who suffer from this disorder and their families. It is estimated that there are approximately two million PBA patients in the U.S., and we are confident of the market potential of the therapeutic area.

Clinical trials are currently underway for **AVP-786**, a combination of deuterated dextromethorphan and low-dose quinidine, for the treatment of agitation in patients with Alzheimer's disease, symptoms associated with residual schizophrenia, and adjunctive treatment of major depressive disorder.

**ONZETRA Xsail (AVP-825)**, a new sumatriptan nasal powder, was approved by the U.S. FDA in January 2016 for the acute treatment of migraine. More than 37 million people are estimated to suffer from migraine in the U.S., but there are indications that many people are not satisfied with existing treatments.\*<sup>4</sup> **ONZETRA Xsail** will be sold by Avanir to address this unmet medical needs.

The Otsuka Group expects that these Avanir products and its pipeline will make a significant contribution to the Group's medium- and long-term growth.

## Taking on the Challenge of Alzheimer's Disease

The number of patients with the Alzheimer's disease is estimated to exceed 30 million globally,<sup>\*5,6</sup> and it is indicated that the chance of being diagnosed with the disease doubles every five years once people reach the age of 65.\*<sup>7</sup> Moreover, about 50% of people with Alzheimer's disease also develop agitation\*<sup>7</sup>, exhibited by behavioral issues such as verbal abuse, violent behavior and distraction. Such behavior not only impairs functioning in the patient's own daily life but also exacerbates the burden on family and caregivers.

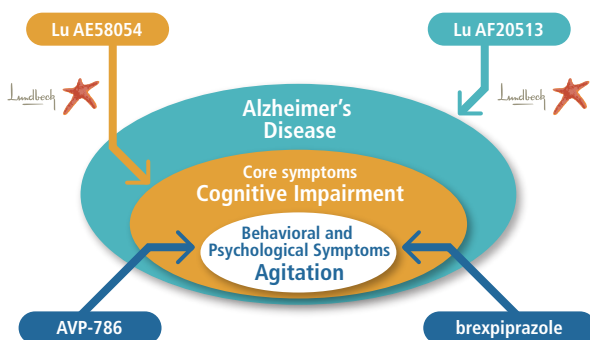
The Otsuka Group is taking a comprehensive approach to fighting Alzheimer's disease by teaming up with H. Lundbeck A/S ("Lundbeck") to develop treatments and integrating the Group's assets in the neurological disease field, an area now further strengthened with the acquisition of Avanir Pharmaceuticals.

With Lundbeck, Phase I trials of **Lu AF20513** and Phase III trials of **Lu AE58054** are underway. **Lu AF20513** is a vaccine candidate that inhibits aggregation and deposition of amyloid beta in the brain, a potential causative factor in the development of Alzheimer's disease, and prevents the disease from progressing. **Lu AE58054** is a selective 5-HT<sub>6</sub> receptor antagonist that curbs the decline in cognitive function, This is used as adjunctive therapy to acetylcholine esterase inhibitors, the existing treatment for Alzheimer's disease. The Group has also initiated Phase I trials of **Lu AF20513** with Lundbeck.

Moreover, the Group is currently carrying out global Phase III trials of **brexpiprazole**, an original new antipsychotic, and **AVP-786**, a combination of deuterated dextromethorphan and low-dose quinidine, a product developed by Avanir as a treatment for the agitation associated with Alzheimer's disease. These two drugs, whose mechanisms of action are completely different, have been granted U.S. FDA fast-track designation for this indication.

The Otsuka Group has positioned this pipeline of Alzheimer's-related dementia as an important growth driver for its medium- and long-term growth beyond 2020.

### Broad Approach to Alzheimer's Disease Treatment



Concept	Compound/ MoA	2016	2017	2018	2019
Suppression of cognitive decline	<b>Lu AE58054</b> • 5-HT <sub>6</sub> receptor antagonist		Phase 3		
Prevention of AD	<b>Lu AF20513</b> • Amyloid β vaccine		Phase 1	Next Step	
	<b>Brexpiprazole</b> • D2 and 5-HT <sub>1A</sub> receptor partial agonist • 5-HT <sub>2A</sub> receptor antagonist		Phase 3		
Improvement in agitation	<b>AVP-786</b> • NMDA receptor antagonist • Serotonin and norepinephrine reuptake inhibitor • Sigma-1 receptor agonist • Neuronal nicotinic receptor antagonist			Phase 3	

\*4 Lipton RB, Stewart WF. Acute migraine therapy: do doctors understand what patients with migraine want from therapy? Headache. 1999; 39(suppl 2): S20-S26

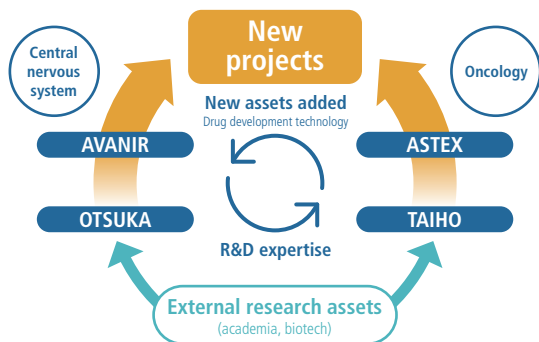
\*5 Alzheimer's Association. "Alzheimer's changes the whole brain" Brain Tour. 2011. Document accessible at: [http://www.alz.org/braintour/alzheimers\\_changes.asp](http://www.alz.org/braintour/alzheimers_changes.asp)

\*6 Barnes DE, Yaffe K. The projected effect of risk factor reduction on Alzheimer's disease prevalence. Lancet Neurology. 2011; 9(1): 819-28.

\*7 Chengxuan Qiu, Miia Kivipelto, Eva von Strauss, Epidemiology of Alzheimer's disease: occurrence, determinants, and strategies toward intervention. Dialogues in Clinical Neuroscience. 2009 June; 11(2): 111-128.

\*8 Agitation in the elderly, Psychiatric Times. 1999; XVI, Issue 1

## Initiatives in R&D Innovation to Secure Sustainable Growth



Astex Pharmaceuticals, Inc. (“Astex”), which has its own fragment-based drug discovery technology, joined the Otsuka Group in 2013, followed in 2015 by Avanir, whose development strengths lie in the neurological disease field. Currently, the Otsuka Group is integrating the expertise and assets built up over many years of R&D activities in the central nervous system and oncology fields with the innovative technologies brought in by Astex and Avanir, and moving ahead with new projects. In the near future, the Group hopes to produce new innovations that help secure sustainable growth.

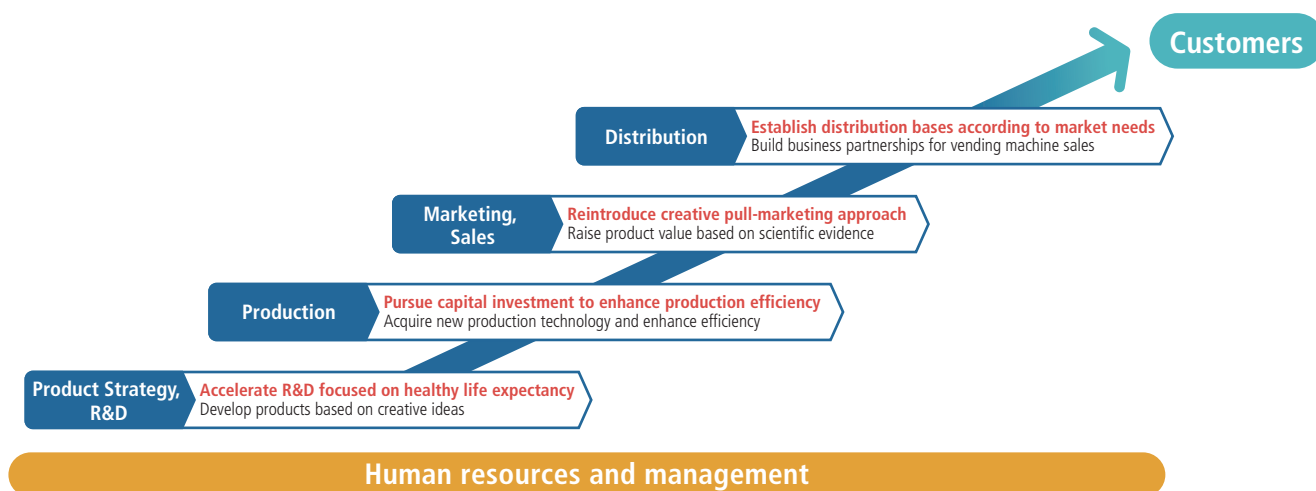


## Progress in Nutraceutical Business

### Steady Progress with Structural Reform and Adaptation Designed to Drive Growth

A thorough review of the total business assets that support the nutraceutical business value chain is one of the key strategies under the Second Medium-Term Management Plan.

In product strategy and R&D, the Otsuka Group continues to develop new products based on its goal of increasing healthy life expectancy by proposing the kind of original ideas that only Otsuka can. In addition, the Group is working to improve the efficiency of its overall manufacturing systems. It has recently acquired natural food supplement manufacturing technology owned by FoodState Inc., which was acquired by Pharmavite in December 2014, and puffed rice cake manufacturing technology and other unique production facilities of BIOCENTURY, which was acquired by Nutrition & Santé (N&S) in October 2015. In addition, the Group has upgraded the **Pocari Sweat** production line in Tianjin, China. In marketing and sales, by raising product value based on the Group’s experience in the pharmaceutical business, as well as scientific evidence, the Group makes original proposals to help consumers experience the benefits of its products. In logistics, the Group has formed a business partnership for vending machine sales with Asahi Soft Drinks Co., Ltd. to raise the value of its vending machines and enhance the brand strength of key products. The Otsuka Group will continue to advance these initiatives to optimize product values with distribution that meets market needs.



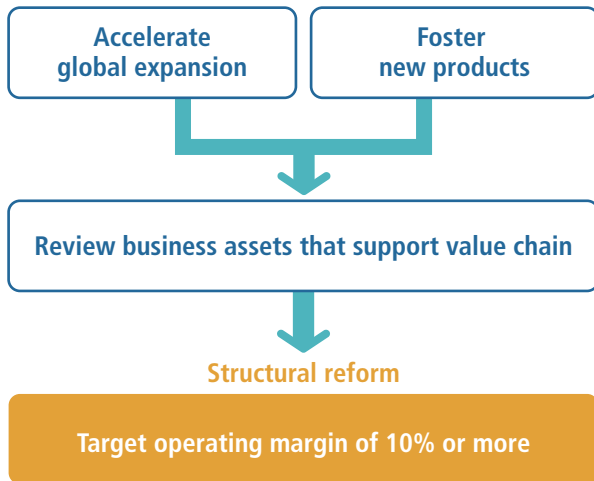


## Further Accelerating Global Expansion

The Second Medium-Term Management Plan positions the growth of global brands such as **Pocari Sweat**, **Nature Made**, **N&S products** and **SOYJOY** outside Japan as one of the Group's most important strategies. Thanks to the success of strategies in various areas, in fiscal 2015 sales outside Japan accounted for 56% of sales in the nutraceuticals business, up from 48% in fiscal 2013. This demonstrates that sales of global products are major drivers of growth in this business. In addition to building up brands in countries where the Group already has a presence, the Group will continue to accelerate its global expansion into new markets that make the most of the Group's networks leading to sustainable growth.

As a result of these initiatives, operating income in the nutraceutical business rose 51.9% over the previous year to ¥31.3 billion in fiscal 2015, yielding an operating margin of 9.5%.

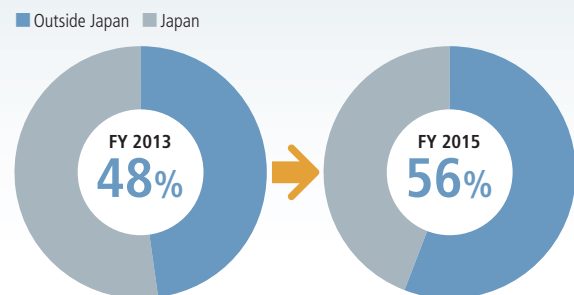
The Group will build a more competitive business structure by further accelerating its global expansion and reviewing its management assets in order to achieve an operating margin of over 10% ahead of the target schedule laid out in the Second Medium-Term Management Plan.



### Steady execution of plan in each area

Area	Brand	Measures	Fiscal 2013-18 CAGR Target	Fiscal 2013-15 CAGR Actual
Asia	Pocari Sweat	Focused investments in Indonesia and China	11%	17%
EU	N&S products	Focus on growing areas such as gluten-free and soy products	6%	10%
U.S.	Nature Made	Foster new categories	5%	20%
JP	Fostering new products	Review business assets through fostering new products	1%	-2%

### Overseas sales ratio in nutraceutical business



# Roadmap of Otsuka's Sustainable Growth



## Achieving Sustainable Growth Beyond Fiscal 2018

In fiscal 2016, Otsuka Holdings forecasts consolidated net sales of ¥1,250 billion (down 13.5% over the previous year) and operating income of ¥70 billion (down 53.9%).

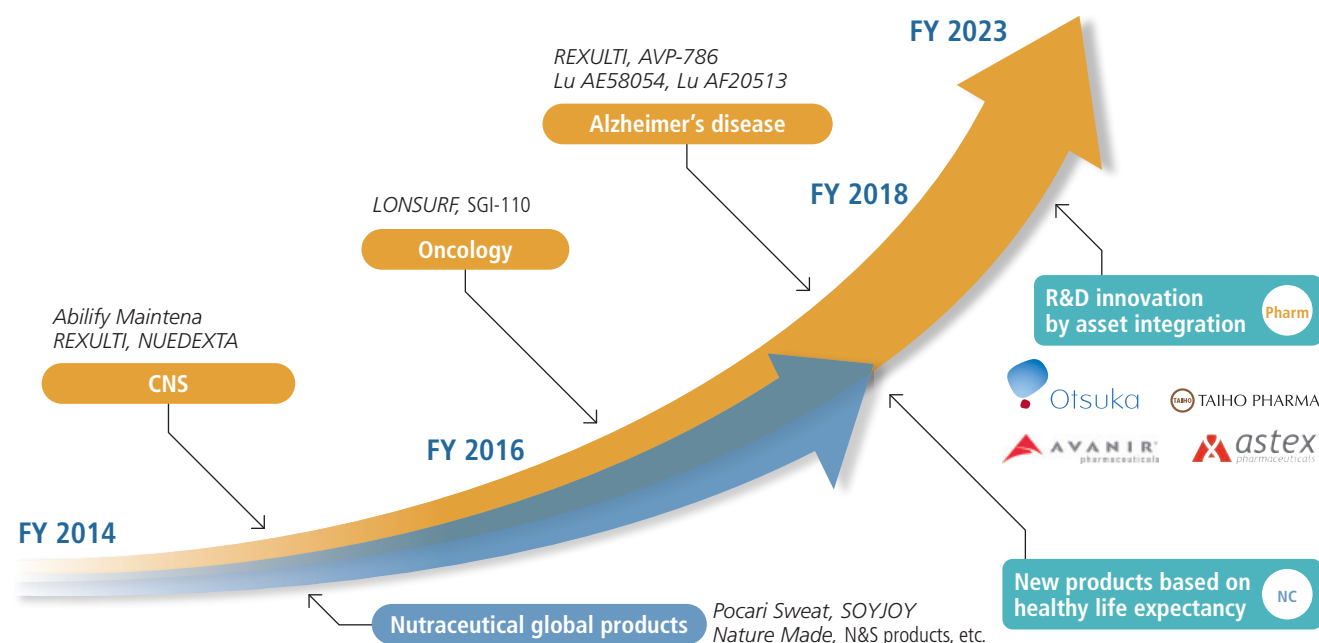
The Group expects lower sales and income in the pharmaceutical business due to the impact of drug price revisions in Japan and the influx of generic drugs in Europe and the U.S. challenging the atypical antipsychotic agent **ABILIFY**. However, it expects new drugs such as **Abilify Maintena**, **REXULTI** and **LONSURF** to post higher sales, continuing the growth from fiscal 2015. For the new drugs leading growth, the Group will build a foundation for maximizing the product value of global products early on in all areas by bringing them to market, adding new indications and reinforcing sales systems. The Japanese business will focus on fostering top brands in each therapeutic area. Moreover, while Otsuka will continue to enhance and maximize cost efficiency as prescribed in the Second Medium-Term Management Plan, it will also continue investments aimed at achieving further growth from fiscal 2016.

The nutraceutical business expects higher revenue from global growth of **Pocari Sweat**, **Nature Made** and **N&S products**, among others, and is targeting an operating margin of over 10% by continuing to invest in customer education and new product cultivation.

The measures to support growth laid out in the Second Medium-Term Management Plan are all progressing in line with the plan. The Otsuka Group expects to ensure growth during and after the period covered by the plan with its development pipeline in the Alzheimer's disease field, as well as the fields of the central nervous system and oncology, and new innovations from the asset integration across the Group. This will lead reliably to sustainable growth beyond 2020.

In accordance with our corporate philosophy "Otsuka-people creating new products for better health worldwide." the Otsuka Group continues to work to become an indispensable contributor to people's health worldwide. We look forward to your continued support.

Tatsuo Higuchi  
President and Representative Director, CEO



# Financial Highlights

					Millions of Yen	Millions of U.S. Dollars (Note 1)
	2012.3 (FY2011)	2013.3 (FY2012)	2014.3 (FY2013)	2014.12 (FY2014) (Note 2)	2015.12 (FY2015)	2015.12 (FY2015)
Net sales	¥1,154,574	¥1,218,055	¥1,452,759	¥1,224,298	<b>¥1,445,227</b>	<b>\$11,983</b>
Operating income	148,662	169,660	198,703	196,529	<b>151,837</b>	<b>1,259</b>
Net income	92,174	122,429	150,990	143,144	<b>84,086</b>	<b>697</b>
Per share of common stock-basic (Yen and U.S. dollars)	165.20	221.90	278.07	264.20	<b>155.13</b>	<b>1.29</b>
Dividends per share (Yen and U.S. dollars)	45.00	58.00	65.00	75.00	<b>100.00</b>	<b>0.83</b>
Capital expenditures	43,302	63,256	178,984	88,226	<b>523,863</b>	<b>4,343</b>
Depreciation and amortization	48,062	45,463	49,746	45,538	<b>71,477</b>	<b>593</b>
R&D expenses	159,230	192,364	249,010	172,851	<b>201,010</b>	<b>1,667</b>
Total assets	1,666,767	1,779,208	2,028,400	2,178,184	<b>2,528,510</b>	<b>20,964</b>
Net assets <sup>(Note 3)</sup>	1,222,765	1,325,071	1,510,760	1,658,600	<b>1,683,436</b>	<b>13,958</b>
Return on equity	7.8%	9.7%	10.8%	9.2%	<b>5.1%</b>	<b>5.1%</b>
Equity ratio	72.5%	73.7%	73.2%	74.7%	<b>65.4%</b>	<b>65.4%</b>
Number of shares issued	557,835,617	557,835,617	557,835,617	557,835,617	<b>557,835,617</b>	<b>557,835,617</b>
Number of employees	24,595	25,330	28,288	29,482	<b>30,638</b>	<b>30,638</b>

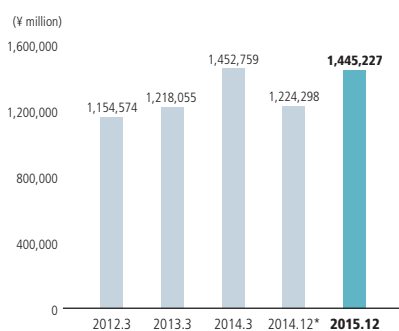
Notes:

1. Financial information in U.S. dollars has been converted at US\$1=¥120.61, the rate as of December 31, 2015.

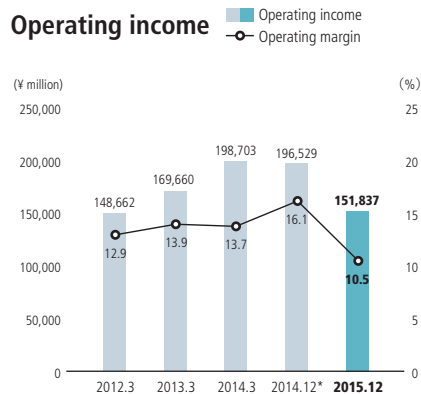
2. Following a resolution on the partial amendment to the Articles of Incorporation at the 6th Annual Shareholders' Meeting held on June 27, 2014, the Company changed its consolidated fiscal year end from March 31 to December 31. Consequently, the consolidated financial results for FY 2014 represent the transitional period of nine months from April 1, 2014 to December 31, 2014.

3. Minority interests have been included in net assets.

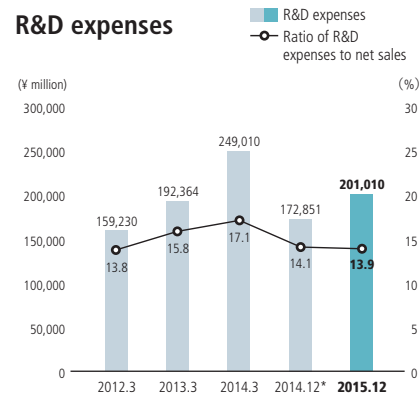
## Net sales



## Operating income

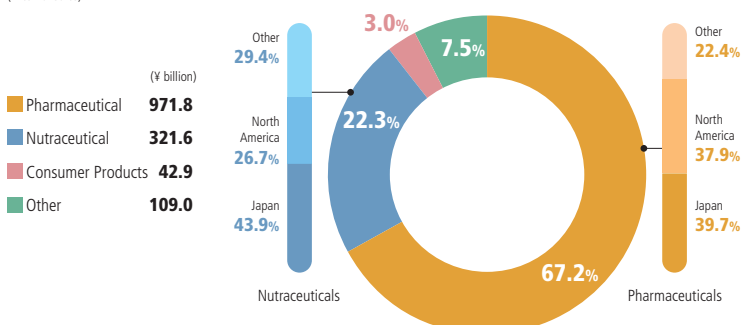


## R&D expenses



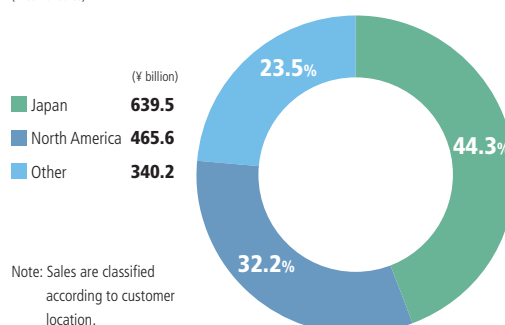
## Sales by business segment

(External sales)



## Sales by geographical area

(External sales)



Note: Sales are classified according to customer location.

\* 2014.12 (FY2014) represents nine months.

## Pharmaceutical Business

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- | Therapeutic Drug Business P.20
- | Clinical Nutrition Business P.26
- | Diagnostics Business P.27
- | Medical Devices Business P.27
- | Research and Development P.28
- | Pipeline Information P.30

## Nutraceutical Business

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- | Japan P.33
- | Global Expansion P.36

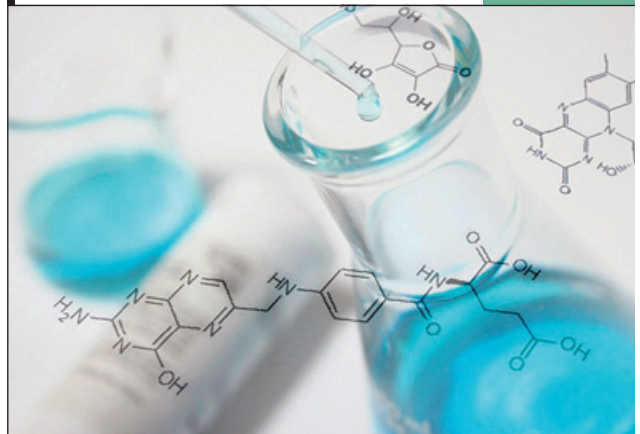
## Consumer Products Business

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## Other Business

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# Pharmaceutical Business



## Segment Overview

The Otsuka Group's pharmaceutical business focuses on the core areas of the central nervous system and oncology in order to address unmet medical needs. Additionally, the Group is engaged in a wide range of other 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

### Diagnostics

Influenza diagnostic agents, *Helicobacter pylori* test kit, Other products

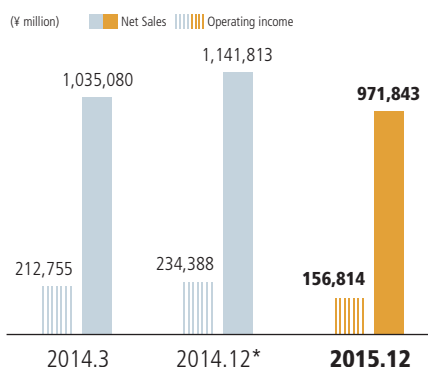
### Clinical nutrition

Intravenous solutions, Enteral nutrition, Contract manufacturing

### Medical devices

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

## 2015 Performance



With the expiration of the patent for the atypical antipsychotic agent *ABILIFY* in Europe and the U.S. in fiscal 2015, net sales in the pharmaceutical business fell 14.9% from the previous year to ¥971,843 million and operating income dropped 33.1% to ¥156,814 million. However, development and marketing of new products that will drive medium- and long-term growth are making steady progress. There are many signs that these products will ensure sustainable growth in the future.

\* As a result of the adoption of a new fiscal year end, the fiscal year ended December 2014 was an irregular nine-month period. For reference, we have included consolidated profit/loss figures (not audited) for all consolidated companies for the period from January 1, 2014 to December 31, 2014. Note: Intersegment sales are included.

# Therapeutic Drug Business

## Central Nervous System

The Otsuka Group continues to take on the challenge of developing treatments for disorders of the central nervous system, while also aiming to maximize the pharmaceutical and commercial value of *Abilify Maintena*, a once-monthly extended-release injectable suspension of *ABILIFY*, and the new antipsychotic *REXULTI*. The Group is accelerating its strategy to expand operations in the central nervous system field by integrating this field with its business foundation in the neurological disease field. This latter area was strengthened with the acquisition of Avanir Pharmaceuticals.

### **ABILIFY** (aripiprazole)

Global sales of the antipsychotic agent *ABILIFY* fell due to the impact of the loss of exclusivity in the U.S. and Europe. Sales in Asia continued to grow sharply overall on the back of higher sales in China and other markets. In Japan, sales of *ABILIFY* rose year on year, supported by an increase in prescriptions and sales share of orally disintegrating tablets for the three approved indications of schizophrenia, manic episodes of bipolar disorder and major depressive disorder.

### **Abilify Maintena**

(extended-release injectable suspension of aripiprazole)

The aripiprazole intramuscular depot formulation *Abilify Maintena* (once-monthly injection) registered significant sales growth in the U.S., supported by efforts to promote the drug's efficacy for the treatment of acutely relapsed adults with schizophrenia, the merits of a ready-to-use prefilled syringe launched in March 2015 and an additional administration route using the deltoid muscle approved in July 2015. In Europe, sales of *Abilify Maintena* continued to increase as the number of countries where it has been launched there expanded to 27 as of December 31, 2015. *Abilify Maintena* was also launched in Australia in March 2015, while in Japan in May 2015, *ABILIFY* for extended-release injectable suspension for intramuscular use was released, adding to the growing number of markets worldwide where the drug is now available and significantly boosting global sales.



### **REXULTI** (brexpiprazole)

The new antipsychotic agent *REXULTI* received approval from the U.S. Food and Drug Administration (FDA) in July 2015 simultaneously for the indications of schizophrenia and adjunctive therapy in major depressive disorder. Prescriptions have been growing steadily since the drug was launched in the U.S. in August 2015.



### **E Keppra** (levetiracetam)

In Japan, the antiepileptic drug *E Keppra*, which is co-promoted with UCB Japan, has achieved firm growth in market share as the top-selling brand\*<sup>1</sup> in the domestic antiepileptic drug market. This reflected growth in prescriptions for pediatric patients and approval in February 2015 for the monotherapy treatment of epileptic partial-onset seizures. Furthermore, in December 2015 a new drip infusion formulation was launched.



### **Neupro Patch** (rotigotine)

*Neupro Patch*, the world's only transdermal dopamine agonist, benefited from increasing understanding of the use of the patch formulation and growing recognition of its effect in improving wearing-off\*<sup>2</sup> symptoms in indications of Parkinson's disease and restless legs syndrome, and is seeing continued strong growth in sales. It has become the top-selling brand\*<sup>1</sup> in the dopamine agonist market in Japan.



### **NUDEXTA** (dextromethorphan, quinidine)

Sales of *NUDEXTA* climbed significantly. *NUDEXTA* was developed by U.S. company Avanir Pharmaceuticals, Inc., which became part of the Otsuka Group in January 2015 and has strengths in drug development in the area of neurological diseases. The drug's stronger sales reflected its increasingly recognized status as the world's first and only treatment for the neurological disease pseudobulbar affect (PBA) on the back of the strengthened sales network in the U.S.



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*NUDEXTA*—The World's First and Only Treatment for the Neurological Disease Pseudobulbar Affect



New Antipsychotic *REXULTI*

P.21

Approved by the FDA as Adjunctive Treatment for Adults with Major Depressive Disorder and as a Treatment for Schizophrenia



\*1: ©2016 IMS Health. Estimated based on "Japan Pharmaceutical Market, January-December 2015." All rights reserved, no reproduction without permission.

\*2: Wearing-off is a complication of dopamine agonist treatments, where symptoms of Parkinson's disease can repeatedly improve and worsen over the course of a day. It is one of the most serious issues affecting the everyday lives of Parkinson's disease sufferers.

## Highlight

### New Antipsychotic *REXULTI* Approved by the FDA as Adjunctive Treatment for Adults with Major Depressive Disorder and as a Treatment for Schizophrenia

In July 2015, Otsuka Pharmaceutical and H. Lundbeck A/S received approval from the U.S. FDA to market *REXULTI* (brexpiprazole) as an adjunctive treatment for adults with major depressive disorder and as a treatment for schizophrenia. *REXULTI* was discovered by Otsuka Pharmaceutical and co-developed with Lundbeck, and this was the drug's first approval, worldwide. It was brought onto the market in the U.S. in August 2015 and is co-marketed by the two companies.

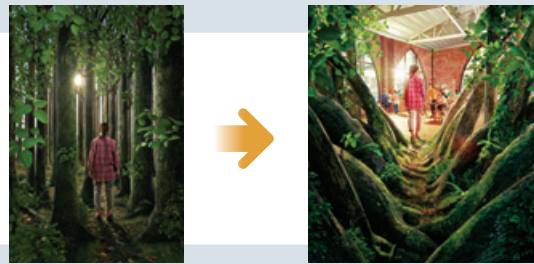
*REXULTI* is a new antipsychotic with a distinct pharmacological effect as a serotonin-dopamine activity modulator (SDAM). It functions through a combination of partial agonist activity on serotonin 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors,

as well as antagonist activity on serotonin 5-HT<sub>2A</sub> receptors.\*<sup>1</sup>

In the U.S., approximately 15 million adults suffer from major depressive disorder and about 2.4 million adults have schizophrenia. Although many use conventional treatments, there is still a need for more effective and well-tolerated alternatives.\*<sup>2</sup> The Group expects that this drug, which has a new mechanism of action, will resolve this frustration and help many patients.

\*1 Maeda, K. *et al.* Pharmacological Profile of Brexpiprazole (OPC-34712): a Novel Serotonin Dopamine Activity Modulator. Poster presentation, American Psychiatric Association annual meeting, May 3-7, 2014.

\*2 The National Alliance of Mental Illness, Mental Illness Facts and Numbers. March 2013. Available at: [http://www2.nami.org/factsheets/mentalillness\\_factsheet.pdf](http://www2.nami.org/factsheets/mentalillness_factsheet.pdf)

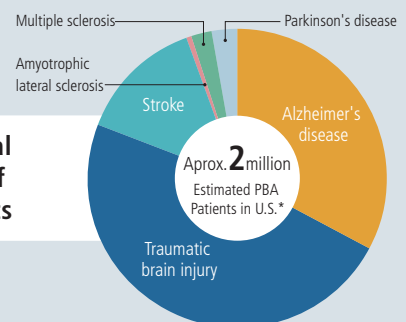


### *NUDEXTA*—The World's First and Only Treatment for the Neurological Disease Pseudobulbar Affect

Pseudobulbar affect (PBA) is a neurological disorder in which individuals cannot control their own feelings or actions. It is characterized by involuntary outbursts of crying in front of others for no reason or laughter in inappropriate situations, and it impedes daily life and often leads to social isolation. There are approximately two million potential PBA patients in the U.S., who have been left without treatment for many years. Avanir Pharmaceuticals released *NUDEXTA*, the world's first PBA treatment, in the U.S. in 2011.

PBA patients usually have underlying conditions such as posttraumatic syndrome after head injuries, multiple sclerosis,

#### Neurological condition of PBA patients



amyotrophic lateral sclerosis, Parkinson's disease, cerebral strokes and Alzheimer's disease. To give patients even greater peace of mind in using this drug, evidence for various underlying conditions was built into the clinical trials.

\* In-house data

## Oncology

The Otsuka Group's oncology operations help in a wide range of fields, including blood cancer, solid carcinomas and supportive care for cancer. Constructive initiatives are underway to enhance the medical value of these products. The Group is working to maximize the product value of **LONSURF** as soon as possible by establishing a marketing structure in the U.S. and working with Servier in Europe.

### TS-1

(tegafur, gimeracil, oteracil)

*TS-1*, a fluoropyrimidine anti-cancer agent, has indications for the treatment of gastric, colorectal, head and neck, non-small cell lung, inoperable or recurrent breast, pancreatic, and biliary tract cancers. The drug is widely used in medical fields due to its clinical efficacy and patient convenience as it is an oral therapy and has multiple formulations. Sales of the drug declined in Japan in fiscal 2015 compared with the same period of the previous year, mainly due to the impact of rival products for gastric cancer. Global sales of the drug fell compared with the same period of the previous year, despite expansion of the number of countries where it is marketed and growing overseas sales on the back of additional drug indications.



### LONSURF

(trifluridine and tipiracil)

*LONSURF*, a new anti-cancer agent, was launched in Japan in May 2014. Prescriptions for the indications of unresectable advanced or recurrent colorectal cancer are rising, leading to steady growth in sales of the drug. In the U.S., *LONSURF* received FDA approval in September 2015 for the treatment of refractory metastatic colorectal cancer and was launched by Taiho Oncology in October 2015. In Europe, the drug was recommended by the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) in February 2016, and approved by the European Commission in April for the same indications.



*LONSURF*—A New Anticancer Drug  
Approved in the U.S. as a Treatment for Refractory Metastatic Colorectal Cancer (mCRC) and Sold by Taiho Oncology  
Licensing Agreement Signed with Servier for Europe and Other Regions



### Abraxane

[paclitaxel (protein-bound particles for injectable suspension)]

*Abraxane*, a paclitaxel albumin-stabilized nanoparticle formulation, grew strongly in fiscal 2015 compared with the same period of the previous year. It was supported by an increase in prescriptions due to its approval for the additional indication of pancreatic cancer in December 2014, following breast cancer, colorectal cancer and non-small cell lung cancer.



### Sprycel

(dasatinib)

The anti-cancer agent *SPRYCEL*, which is being promoted in Japan, the U.S. and Europe in collaboration with Bristol-Myers Squibb, has seen growth in prescriptions worldwide as a first-line treatment for chronic myeloid leukemia. Sales of the drug in fiscal 2015 increased compared with the same period of the previous year.

### Busulfex

(busulfan)

*Busulfex*, an allogeneic hematopoietic stem cell pre-transplanting regimen now sold in more than 50 markets worldwide, has established a standard drug therapy approach as a conditioning agent administered prior to bone marrow transplants in place of total-body radiation. Sales of *Busulfex* in fiscal 2015 increased compared with the same period of the previous year.





## Highlight

### **LONSURF—A New Anticancer Drug Approved in the U.S. as a Treatment for Refractory Metastatic Colorectal Cancer (mCRC) and Sold by Taiho Oncology Licensing Agreement Signed with Servier for Europe and Other Regions**



In September 2015, Taiho Oncology, Taiho Pharmaceutical's U.S. subsidiary, received approval from the U.S. FDA to market *LONSURF* (nonproprietary names: trifluridine and tipiracil), an oral combination anticancer drug, as a treatment for refractory metastatic colorectal cancer (mCRC).<sup>\*1</sup> Taiho Oncology brought *LONSURF* onto the market in October. This is the first product for which Taiho Pharmaceutical has obtained approval in the U.S. The approval was based on results from the global Phase III RECURSE trial, and the results were published in *The New England Journal of Medicine* (May 14, 2015 edition). Colorectal cancer is the third most common type of cancer and the second leading cause of cancer-related deaths in the U.S.<sup>\*2</sup> The approval of *LONSURF* gives patients in the U.S. a new option.

In Europe, the European Commission approved *LONSURF* for the same indications in April 2016. In Europe and other areas (other than North America and Asia), Taiho Pharmaceutical entered into a licensing agreement with Servier in 2015 covering development and marketing rights. This partnership between the two companies will lead to greater support for patients all over the world.

<sup>\*1</sup> Metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

<sup>\*2</sup> American Cancer Society; What are the key statistics about colorectal cancer?  
<http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics>

### **Launch of the Novel Antitumor Agent *Yondelis IV Infusion***

In December 2015, Taiho Pharmaceutical introduced the anti-cancer agent *Yondelis IV Infusion* in Japan. This drug was developed by the Spanish company PharmaMar, S.A. Taiho Pharmaceutical entered into a licensing agreement with PharmaMar in 2009 to develop and market the drug in Japan. Taiho Pharmaceutical received approval to manufacture and market the drug for the indication of soft tissue sarcoma, an orphan disease with an estimated patient number of about 5,000 in Japan.<sup>\*1</sup> The drug has been approved in 78 countries and regions, including the U.S., Europe, South America and Asia.<sup>\*2</sup> Taiho Pharmaceutical expects to make significant contributions to patient treatment by offering this new treatment option for soft tissue sarcoma, a condition with high unmet medical needs.



<sup>\*1</sup> Calculated by subtracting the 1,000 "mesothelioma" patients from the 6,000 "mesothelial and soft tissue malignancy" patients quoted in the MHLW Patient Survey (2011).

<sup>\*2</sup> As of October 2015

### **MSD and Taiho Pharmaceutical Enter into Co-Promotion Agreement in Japan for Pembrolizumab, MSD's Immune Checkpoint Inhibitor (anti-PD-1 therapy)**

In April 2016, Taiho Pharmaceutical concluded a co-promotion agreement in Japan with MSD K.K. for pembrolizumab (nonproprietary name, development code: MK-3475), an immune checkpoint inhibitor (anti-PD-1 therapy) for which MSD has filed an application for approval in Japan. Under this agreement, Taiho will co-promote pembrolizumab with MSD, while MSD will manufacture and sell it.

In Japan, MSD submitted an application for authorization to manufacture and sell pembrolizumab for the treatment of patients with unresectable or metastatic melanoma in December 2015, and for the treatment of patients with unresectable advanced or recurrent non-small cell lung cancer in February 2016. Clinical trials are currently underway for the treatment of bladder cancer, lung cancer, breast cancer, gastric cancer, head and neck cancer, multiple myeloma, esophageal cancer, colorectal cancer, Hodgkin's lymphoma and advanced solid tumors. In October 2015, pembrolizumab was designated as one of the medicines included in the Japan's Ministry of Health, Labour and Welfare's Sakigake Fast-Track Review for the treatment of unresectable advanced or recurrent gastric cancer.

MSD and Taiho Pharmaceutical will seek to further assist patients and healthcare providers in the oncology field by building a close partnership while co-promoting pembrolizumab, a promising new option for cancer treatment.

## Cardiovascular System

*Samsca/JINARC*, a vasopressin receptor 2 antagonist, is the world's first therapeutic drug for autosomal dominant polycystic kidney disease (ADPKD), for which treatment was previously unavailable. In addition to growth as an aquaretic, its contribution as an ADPKD treatment will spur global expansion.

## Other Areas

In the field of the digestive system, prescriptions for *TAKECAB*, which has been co-promoted in Japan with Takeda Pharmaceutical Co., Ltd. since February 2015, are steadily increasing. In the ophthalmic field, sales of *Mucosta Ophthalmic Suspension UD 2%*, a treatment for dry eyes, are also growing. In the infectious disease field, *Deltyba*, a new anti-tuberculosis drug, is now available in Europe, Japan and South Korea.



### *Samsca/JINARC* (tolvaptan)

*Samsca* is gaining more acceptance among medical specialists due to its value as an oral aquaretic agent, supporting a large increase in global sales in fiscal 2015 compared with the same period of the previous year. Globally the drug (*Samsca/JINARC*) has also started to be used as the world's first drug for autosomal dominant polycystic kidney disease ("ADPKD"), an intractable kidney disease. In Japan, the drug was approved for this additional indication in March 2014, and prescriptions have increased as understanding of the drug has increased. The drug was also approved for the treatment of ADPKD in Europe in May 2015. As of March, 2016, *Samsca/JINARC* was available for both indications in 22 markets worldwide.

## Highlight

### Otsuka Releases *JINARC*, the First-Ever ADPKD Treatment Approved in Europe

Otsuka Pharmaceutical received approval in May 2015 to market *JINARC* (nonproprietary name: tolvaptan) as a treatment for adults with ADPKD. This was the first time that a pharmaceutical therapy for ADPKD had been approved in Europe. As of March 2016, *JINARC* had been released in Germany, the U.K., Norway, Luxembourg and Austria, and sales continue to be extended successively into other countries.

ADPKD is a chronic and progressive genetic disease which causes cyst proliferation and growth in the kidneys, leading to an increase in kidney size. This leads to complications such as chronic and acute pain, hypertension, and kidney failure, which ultimately requires dialysis or renal transplant. An estimated 200,000 people suffer from ADPKD in Europe.

Tolvaptan was developed by Otsuka Pharmaceutical over 26



years, and was released in 2009 as an aquaretic with vasopressin  $V_2$  receptor antagonist effects. In addition Otsuka Pharmaceutical discovered that vasopressin  $V_2$  receptor antagonists also slowed the progression of ADPKD, which had no treatment at that time, and decided to develop it as an ADPKD treatment. It was first approved for use in Japan in 2014, followed by other countries.

## Highlight

### Otsuka Pharmaceutical Builds Private-Public Partnership to Ensure Worldwide Access to Delamanid

In February 2016, Otsuka Pharmaceutical formed a public-private partnership with Stop TB's Global Drug Facility (GDF).

*Deltyba* (nonproprietary name: Delamanid) is an anti-bacterial drug developed by Otsuka Pharmaceutical. It has a novel mechanism of action that impedes the generation of mycolic acid, a major constituent of *Mycobacterium tuberculosis* cell walls. This bactericidal agent is used in Europe, Japan and South Korea against multidrug-resistant tuberculosis (MDR-TB). The global partnership aims to improve access to delamanid in countries in which TB is epidemic.

In this partnership, any country that is eligible for TB financing from the Global Fund to Fight AIDS, TB and Malaria and follows the World Health Organization (WHO) Guidelines for the proper management of MDR-TB can apply to GDP to use delamanid in their treatment programs. This means that over 100 countries may now be eligible to access delamanid.

This public-private partnership goes beyond the supply of delamanid and provides a framework to provide education and

"FIGHTBACK" is a magazine for enlightenment of tuberculosis published by Otsuka Pharmaceutical and the European Respiratory Society. It contains messages to encourage patients who have been treated for tuberculosis and the people involved.



training support, technical assistance and treatment infrastructure to ensure that delamanid is appropriately incorporated in MDR-TB treatment programs.

The WHO published the policy guidelines, The Use of Delamanid in the Treatment of Multidrug-Resistant Tuberculosis in 2014, and in 2015 delamanid was added to the WHO's Essential Medicines List.

The Stop TB Partnership is made up of international organizations such as the WHO, government organizations, private companies and patient groups, and was established in 2001 to eradicate TB. GDF was established as a sub-organization to supply anti-tuberculosis drugs to developing countries in which TB is epidemic.

## Global Operation of Otsuka Group's Therapeutic Drug Business

Otsuka Group's therapeutic drug business is demonstrating the value of its unique approach while respecting the diversity of cultures in which it operates. We are determined to keep contributing to better health for people worldwide.



### Operating Companies

Therapeutic drug business

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

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*, *Abilify Maintena* and *REXULTI*, the aquaretic *Samsca*, the hematopoietic stem-cell pre-transplanting regimen *Busulfex*, the *BreathTek* kit for diagnosing *Helicobacter pylori* infection, and the antiplatelet agent *Pletal*.



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

Founded in 1998, Otsuka Pharmaceutical Europe Ltd. is the central office for European marketing and sales of pharmaceuticals and medical devices. The company currently sells products such as the aquaretic *Samsca*, the ADPKD treatment *JINARC*, the antipsychotic drugs *ABILIFY* and *Abilify Maintena*, the antiplatelet agent *Pletal*, and the apheresis device for leukocyte adsorption *Adacolumn*.

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

In 2002, Taiho Pharmaceutical established Taiho Oncology in the U.S. to serve as its global development hub and in-house marketing platform for anti-cancer drugs. The new anti-cancer drug *LONSURF* was approved in September 2015 by the FDA, and was introduced in the U.S. market by Taiho Oncology in October 2015.



# Clinical Nutrition Business

The clinical nutrition business is handled primarily by Otsuka Pharmaceutical Factory, whose mission is to be the best partner of patients and healthcare professionals in the field of clinical nutrition. The achievements of this business include Japan's first plastic bottles utilizing advanced sterilization technology, aseptic, easy-use bags for administration of high-calorie infusion solutions, antibiotic solution kits, and a range of other products that accurately meet the needs of healthcare professionals.

*ELNEOPA*, a high-calorie TPN solution, has seen a steadily growing market share. This can be attributed to its recognition as a pharmaceutical preparation for TPN kits containing the essential trace elements recommended in the 2013 JSPEN Guidelines and to the acclaim it has earned for its effect in reducing the risk of infection and time required to prepare TPN mixtures.

Outside Japan, intravenous solution manufacturing bases have been established in eight countries, primarily in Asia,\* as part of the Group's global expansion.



\*: Including affiliates accounted for by the equity method and non-consolidated companies

Operating Companies		Clinical Nutrition Business	
<p><b>China Otsuka Pharmaceutical Co., Ltd.</b> (Tianjin, China) (Affiliated company)</p> <p>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 approximately 1,400 employees and handles basic intravenous solutions, preparations in ampoule, and ophthalmic solutions.</p> 	<p><b>Otsuka Ateco Pharma Egypt</b> (El Obour City, Egypt) (Unconsolidated subsidiary)</p> <p>In June 2014, Egypt Otsuka Pharmaceutical acquired Ateco Pharma Egypt, a company involved in the manufacture and sales of intravenous solutions in Egypt. In order to meet demand in this growing market, the company is working with Otsuka Pharmaceutical Factory to provide high-quality intravenous solutions to countries in the Middle East and Africa.</p> 		
<p><b>Claris Otsuka Ltd.</b> (Ahmedabad, India)</p> <p>On July 31, 2013, Otsuka Pharmaceutical Factory, Mitsui &amp; Co., and Claris Life Sciences, 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 value-added clinical nutrition products, the company aspires to contribute to the advancement of medical care in India.</p> 			

## Highlight

### First Novel Antiseptic for External Use in over 50 Years Otsuka Pharmaceutical Factory Launches Olanedine, an Antiseptic for External Use

In September 2015, Otsuka Pharmaceutical Factory launched *Olanedine Antiseptic Solution 1.5%*, *Olanedine Solution 1.5% Antiseptic Applicator 10 mL*, and *Olanedine Solution 1.5% Antiseptic Applicator 25 mL*, three antiseptics for external use.

In recent years, resistance to marketed antiseptics for external use has been reported in bacteria including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE) and *Pseudomonas aeruginosa*, and the development of new antiseptics for external use effective against such bacteria has been sought. *Olanedine* is a novel biguanide-based antiseptic with olanexidine gluconate as the active ingredient. Studies of *In vitro* efficacy show that it exerts a significant bactericidal effect against bacteria deemed to be antiseptic-resistant, such as MRSA, VRE, *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Burkholderia cepacia*, in addition to various Gram-positive and Gram-negative bacteria. In addition, Otsuka Pharmaceutical Factory used its own technology to improve the applicators widely used in U.S. medical institutions and succeeded in developing Japan's first applicator-type antiseptic. This product was launched as a simple, sanitary applicator, and won the 2015 Good Design Award. Otsuka hopes that this lineup will be used in medical care to help prevent infection in patients.



## Diagnostics Business

The diagnostics business focuses on the research, development, manufacture, and sale of intracorporeal and extracorporeal clinical diagnostic agents and research-use reagents. Released in December 2002, *UBIT* is a diagnostic agent which can detect the presence of *Helicobacter pylori* in the stomach. It is used widely in medical facilities. In February 2013, *UBIT* was approved for the additional indication of gastritis caused by *Helicobacter pylori* infection and significantly expanded market share. The popularity of the influenza virus test kit *Quick Navi-Flu* is also on the rise due to growing demand for the early identification of colds and influenza now that more anti-influenza drugs are available. In addition, the *Major BCR-ABL mRNA Measurement Kit*, approved for health insurance coverage in Japan starting in April 2015, is utilized as an external testing kit which meets international standards to assist with diagnosis and monitoring of treatment effectiveness for chronic myeloid leukemia.



### Core products

Brand name	Category	Company
UBIT	Diagnostic agent for <i>Helicobacter pylori</i>	Otsuka Pharmaceutical
Quick Navi-Flu	Influenza virus test kit	Otsuka Pharmaceutical
Major BCR-ABL mRNA Measurement Kit	A Marker to Monitor Treatment Effectiveness For Chronic Myeloid Leukemia	Otsuka Pharmaceutical

## Medical Devices Business

Otsuka Medical Devices was established in 2011 in order to strategically integrate the Otsuka Group's medical device business, which was developed with the aim of contributing to people's health using a new approach, different from that of the therapeutic drug business, based on total healthcare. Its subsidiary, JIMRO, manufactures and markets *Adacolumn*, an apheresis device for granulocyte adsorption used to treat inflammatory bowel disease and intractable skin disease. Other major affiliates include Microport Scientific Corporation (fields including cardiovascular disease and artificial joints) and Achieva Medical (Shanghai) (cerebral vascular field), both based in Shanghai, China, and Era Endoscopy (self-propelling robotic colonoscopy) based in Pisa, Italy. As a new business, Otsuka has begun developing intravesical urine volume sensors in the urology field, and has established a new company in this field, Liliom Otsuka Co., Ltd. The Otsuka Group is confident that providing innovative medical equipment like this will contribute not only to the lives of many patients but also those who care for them.



### Core products

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

## Highlight

### *Lilium α-200*, a Continuous Urine Volume Sensor, Launched in Japan

Otsuka Medical Device established Liliom Otsuka in January 2015 to develop products for incontinence care, an area in which there are significant social and medical needs. In November 2015, the *Lilium α-200*, a continuous, non-invasive bladder urine volume sensor, was released. This product makes it possible to continuously monitor urination schedules for patients who have lost the urge to urinate for various reasons. This is expected to give patients independence in urinating and allow them to return home. The spread of this product will raise quality of life for many people, as well as reduce workload and improve efficiency for those involved in nursing and caregiving. This product contributes to medical care that increases dignity for patients.



# Research and Development

## Otsuka Pharmaceutical

Ever since Otsuka Pharmaceutical established its research & development (R&D) division in 1971, the company has been carrying out R&D to create new pharmaceuticals for the global market. The company continues to pursue total innovation in R&D, with the development of treatments for diseases of the central nervous system and oncology given the greatest priority. Cardiovascular, gastrointestinal and respiratory ailments, infectious diseases and the areas of ophthalmology and dermatology are also key areas for the company. Researchers in the company's laboratories make the most of their own strengths and individuality and refine their skills with one another in an environment of open discussion. The compounds produced in the drug discovery laboratories, based primarily in Tokushima, are developed via Otsuka Pharmaceutical's own global clinical development network, which reaches across Japan, the U.S., Europe and Asia. The company is also proactive in forming alliances with major pharmaceutical companies and venture companies to capitalize on mutual strengths, then carrying out R&D with world-class quality and speed while complementing its partner's operations. New drug development aimed at unmet needs is also moving forward in the fields of Alzheimer's disease and chronic/acute myeloid leukemia.

### Tokushima Research Institute

The Tokushima Research Institute, located in the region in which Otsuka Pharmaceutical was established, carries out research in the areas of the central nervous system, gastrointestinal and respiratory ailments, cardiovascular system, and infectious diseases to produce creative and innovative drugs.



### Astex Pharmaceuticals, Inc.

Astex Pharmaceuticals consists of its research headquarters in Cambridge, England, known for its fragment-based drug design technology, and its California clinical oncology R&D department, which focuses on methylation inhibitors. Astex became a subsidiary of Otsuka Pharmaceutical in October 2013.



### Otsuka Pharmaceutical Development & Commercialization

Working with Otsuka Pharmaceutical's Drug Discovery Division, Otsuka Pharmaceutical Development & Commercialization functions as the global development hub for pharmaceuticals by carrying out clinical trials of treatments for a wide range of disorders in the fields of the central nervous system, cardiovascular system, oncology, infectious diseases and ophthalmology.



### Avanir Pharmaceuticals, Inc.

Established in 1988, Avanir Pharmaceuticals develops and markets pharmaceuticals for disorders of the central nervous system. Avanir became a subsidiary of Otsuka Pharmaceuticals in January 2015.

## Taiho Pharmaceutical

Taiho Pharmaceutical is a global specialty pharmaceutical company that carries out research and development in the areas of oncology, allergy/immunology, and urology. The company's Discovery and Preclinical Research Division (Tsukuba Area, Japan) functions as a base for drug discovery and building an R&D network focused on new medical processes. This division closely coordinates with the Discovery and Preclinical Research Division (Tokushima Area, Japan) and the Clinical Development Division. In the field of oncology, which is the company's main focus, Taiho Pharmaceutical carries out global development of its mainstay anticancer agents in Japan, the U.S., Europe and Asia, and engages in R&D with the aim of providing innovative new drugs to the world.

### Discovery and Preclinical Research Division (Tsukuba Area/Tokushima Area, Japan)

In the Tsukuba Area, the Discovery and Preclinical Research Division analyzes unmet medical needs, conducting basic research to discover innovative new drug candidates. At its Tokushima Area's facilities, the company evaluates the effectiveness and safety of the new drug candidate compounds it has identified, bridges to clinical trials, and carries out the research needed to ensure that its treatments suit individual patients, and are highly effective and have few side effects.



### Taiho Oncology, Inc.

In 2002, Taiho Pharmaceutical established Taiho Oncology in the U.S. to serve as its global development hub for anticancer drugs. The team of experts here works together with Japanese staff and develops new drugs that can enhance cancer treatment around the world, collaborating with medical professionals and organizations in the U.S. and Europe.

## Otsuka Pharmaceutical Factory

Otsuka Pharmaceutical Factory carries out R&D for products that create new value and will fulfill unmet needs in the perioperative field and regenerative medicine field, as well as pharmaceuticals in the clinical nutrition business, such as the mainstay intravenous solutions, which are vital to the practice of medicine. For example, the company develops products that prevent adhesion, which frequently occurs after surgery and can cause abdominal pain and intestinal obstructions, and has developed the Bioengineered Pancreas Islet, which has potential to become a basic treatment for diabetes patients. With such products, the company always takes the patient's point of view and develops innovative pharmaceuticals and medical devices under the mantra of JISSHO ("Proof through Execution") and SOZOSEI ("Creativity").

The company also focuses on the development of medical foods used in medical settings. This includes the development of safe and effective products that meet the needs of patients and medical professionals, such as *OS-1*, Japan's first oral rehydration solution that is compatible with the approach to oral rehydration therapy advocated by the World Health Organization (WHO). The company will continue its work with the aim of contributing to the public's health.



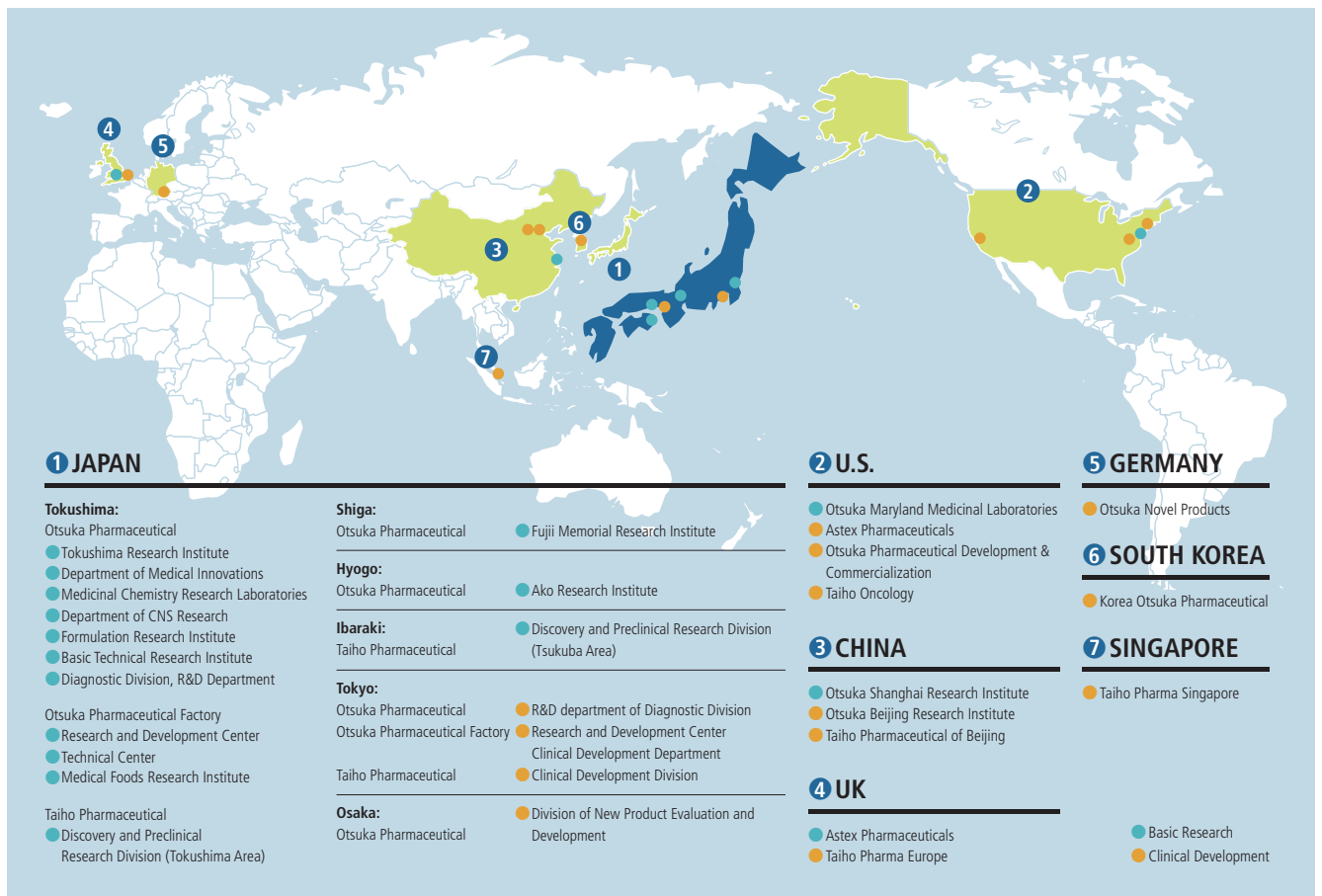
### Research and Development Center

The company established the Naruto Research and Development Center in Naruto City, Tokushima where the Otsuka Group has its origins. The Center conducts R&D for pharmaceuticals and medical devices in clinical nutrition, the perioperative field and regenerative medicine while working with the research center responsible for clinical research in Tokyo.



### Medical Foods Research Institute

In June 2013, the Medical Foods Research Institute was formed to focus on developing products for the global market, particularly Asia. In May 2014, the Medical Foods Research Institute Building was opened on headquarters premises in Naruto, Tokushima. This move consolidated research and formulation development functions in one location, creating an R&D structure ready to develop new products rapidly.



# Pipeline Information (As of March 31, 2016)

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status				
						Phase I	Phase II	Phase III	Filed	Approved
<b>Central nervous system, neurological disorders</b>						Phase I	Phase II	Phase III	Filed	Approved
OPC-14597 <ABILIFY*> <Abilify Maintena*> Depot injection	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Autism / Oral	JP					
				Agitation associated with dementia of the Alzheimer's type / Oral	JP					
				Bipolar I / Depot injection	JP, U.S., EU					
L059 <E Keppra>	levetiracetam	UCB	Anti-epileptic drug	Epilepsy (generalized onset seizures) / Oral, Injection	JP					
				Major depressive disorder / Oral	EU					
OPC-34712 <REXULTI*>	brexpiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Schizophrenia / Oral	JP, EU					
				Agitation associated with dementia of the Alzheimer's type / Oral	U.S., EU					
				Posttraumatic stress disorder (PTSD) / Oral	U.S., EU					
Lu AE58054	idalopirdine	Lundbeck	selective Serotonin 5-HT <sub>6</sub> receptor antagonist	Alzheimer's disease / Oral	U.S., EU					
ASC-01	aripiprazole, sertraline	Otsuka Pharmaceutical	Dopamine partial agonist / Selective serotonin reuptake inhibitor	Major depressive disorder / Oral	JP, Asia					
AVP-923	dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Serotonin and norepinephrine reuptake inhibitor / Sigma-1 receptor agonist / Neuronal nicotinic receptor antagonist	Dyskinesia associated with Parkinson's disease / Oral	U.S.					
AVP-786	deuterium-modified dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Serotonin and norepinephrine reuptake inhibitor / Sigma-1 receptor agonist / Neuronal nicotinic receptor antagonist	Major depressive disorder / Oral	U.S.					
				Agitation associated with dementia of the Alzheimer's type / Oral	U.S., EU					
				Residual schizophrenia symptoms / Oral	U.S.					
AVP-825 <ONZETRA Xsail*>	sumatriptan	Avanir	Serotonin 5-HT <sub>1B/1D</sub> receptor agonist	Acute migraine / Nasal powder	U.S.					
TAS-205		Taiho Pharmaceutical	Prostaglandin D synthase-inhibitor	Duchenne Muscular Dystrophy (DMD) / Oral	JP					
Lu AA36143	nalmefene	Lundbeck	Opioid receptor antagonist	Lowering of alcohol consumption in alcohol dependence / Oral	JP					
Lu AF20513		Lundbeck	$\beta$ -amyloid vaccine	Preventing progression of Alzheimer's dementia / Injection	EU					
<b>Oncology</b>						Phase I	Phase II	Phase III	Filed	Approved
S-1 <TS-1> <Teysuno*>	tegafur, gimeracil, oteracil	Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Uterocervical cancer / Oral	JP, Asia					
TAS-102 <LONSURF*>	trifluridine, tipiracil	Taiho Pharmaceutical	Anti-cancer	Colorectal cancer / Oral	EU					**
				Gastric cancer / Oral	JP, U.S., EU					
TAS-118	tegafur, gimeracil, oteracil, folinate	Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Pancreatic cancer / Oral	JP, Asia					
				Gastric cancer / Oral	JP, Asia					
<SATIVEX*>	nabiximols	GW Pharmaceuticals	Cannabinoid (THC, CBD)	Cancer pain / Oral spray	U.S.					
SGI-110	guadecitabine	Astex	Anti-cancer	Ovarian cancer / Injection	U.S., EU					
				Hepatocellular carcinoma / Injection	U.S., EU					
				Acute myeloid leukemia, Myelodysplastic syndrome / Injection	U.S.					
				Acute myeloid leukemia / Injection	U.S., EU JP, Asia					
AT13387		Astex	Anti-cancer (Molecular-targeted drug)	NSCLC / Injection	U.S., EU					
AT7519		Astex	Anti-cancer (Molecular-targeted drug)	Multiple myeloma / Injection	U.S.					
ASTX727		Astex	Anti-cancer	Myelodysplastic syndrome / Oral	U.S.					
ASTX660		Astex	Anti-cancer (Molecular-targeted drug)	Solid tumors, Lymphomas / Oral	U.S.					



Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status				
						Phase I	Phase II	Phase III	Filed	Approved
OPB-111077		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	U.S., Asia					
OPB-111001		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	EU					
TAS-114		Taiho Pharmaceutical	Anti-cancer (Antitumor enhancer)	Solid tumors / Oral	JP, U.S., 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					
TAS-117		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP					
TAS-119		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	U.S., EU					
TAS-120		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP, U.S., EU					
TAS-121		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP					
TAS3681		Taiho Pharmaceutical	Anti-androgenic agent	Prostate cancer / Oral	U.S., EU					
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					
<b>Cardiovascular</b>						Phase I	Phase II	Phase III	Filed	Approved
OPC-41061 <Samsca* / JINARC*>	tolvaptan	Otsuka Pharmaceutical	Vasopressin V <sub>2</sub> receptor antagonist	Hepatic edema / Oral	Asia					
				Autosomal dominant polycystic kidney disease / Oral	U.S.					
				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, U.S.	
<b>Other areas</b>						Phase I	Phase II	Phase III	Filed	Approved
TAC-202	bilastine	Faes Farma	Histamine H <sub>1</sub> receptor antagonist	Allergic rhinitis / Oral	JP					
				Chronic urticaria, Pruritus associated with skin disease / Oral	JP					
OPC-67683 <Delyba*>	delamanid	Otsuka Pharmaceutical	Anti-tuberculosis agent	Multidrug-resistant tuberculosis / Oral	U.S.					
				Multidrug-resistant tuberculosis for pediatrics / Oral	EU					
OPC-12759E <Mucosta Ophthalmic Suspension>	rebamipide	Otsuka Pharmaceutical	Mucin-production enhancing agent	Dry eyes / Eye drops MD (Multi Dose)	JP					
OPF-105	Amino acid, carbohydrate, and fat emulsion injection with electrolytes and vitamins	Otsuka Pharmaceutical Factory	Protein and amino acid preparation	Peripheral parenteral nutrition solution / Injection	JP					
OPF-108	Amino acid and carbohydrate with electrolytes and vitamins	Otsuka Pharmaceutical Factory	Protein and amino acid preparation	Total parenteral nutrition / Injection	JP					
ACU-4429	emixustat	Acucela	Visual cycle modulator	Dry AMD / Oral	U.S.		Phase IIb / III			
OPA-6566		Otsuka Pharmaceutical	Adenosine A <sub>2b</sub> receptor agonist	Glaucoma / Eye drops	U.S.		Phase I / II			
OPC-1085EL	carteolol, latanoprost	Otsuka Pharmaceutical	$\beta$ receptor antagonist / PGF <sub>2<math>\alpha</math></sub> analogue	Glaucoma / Eye drops	JP					
OPA-15406		Otsuka Pharmaceutical	PDE4 inhibitor	Atopic Dermatitis / Ointment	U.S.					
OPS-2071		Otsuka Pharmaceutical	New quinolone base	<i>Clostridium difficile</i> infection, enteric infection / Oral	JP, Asia					
<b>Diagnostics</b>						Phase I	Phase II	Phase III	Filed	Approved
C13-CAC	calcium (13C)	Otsuka Pharmaceutical	13C-Calcium Carbonate breath test	For measurement of gastric acidity / <i>In-vivo</i> diagnostic agent	JP					

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

\*: Product names used outside Japan.

\*\* : Events after March 31, 2016: TAS-102/Colorectal cancer: approved in April in EU.

# Nutraceutical Business



## Segment Overview

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

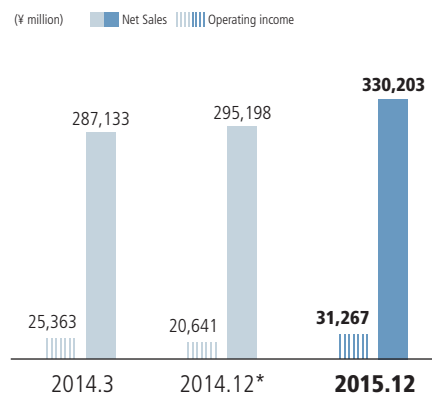
Functional beverages and foods

Cosmetics\*

\* Cosmetics + medicine

OTC products, Quasi-drugs

## 2015 Performance



In fiscal 2015, the nutraceutical business achieved steady growth in sales of *Pocari Sweat* and *Calorie Mate* in Japan, and also made major contributions to the continuing growth of the vitamin business in the U.S. and to higher earnings for nutritional products and others in Europe. As a result, sales rose 11.9% over the previous year to ¥330,203 million, and operating income climbed 51.5% to ¥31,267 million.

\* As a result of the adoption of a new fiscal year end, the fiscal year ended December 2014 was an irregular nine-month period. For reference, we have included consolidated profit/loss figures (not audited) for all consolidated companies for the period from January 1, 2014 to December 31, 2014. Note: Intersegment sales are included.

# Japan

Sales volume of the *Pocari Sweat* electrolyte supplement drink increased compared with the same period of the previous year, despite a weak domestic market for sports drinks. The result reflected demand from users, stimulated in part by efforts to provide health information based on scientific evidence.

Total brand sales volume for the carbonated nutritional drink *Oronamin C Drink* declined slightly year on year, despite steady growth in the number of stores that stock *Oronamin C ROYALPOLIS*, which was relaunched in March 2015.

Sales volume for the balanced nutrition food *Calorie Mate* increased compared with the same period in the previous year. This reflected enhanced efforts to increase consumer understanding of the product and secure new users, mainly targeting students preparing for entrance exams and office workers.



## Pocari Sweat

A functional drink to quickly replenish water and ions (electrolytes), based on the concept of a beverage to support the body during sweating. In 2016, new *Pocari Sweat Ion Water* was released, a product designed to quench everyday thirst and support physical conditioning on a daily basis.



## Oronamin C Drink

*Oronamin C Drink*, now sold in nine countries and regions, is a carbonated nutritional drink that is a convenient, delicious source of Vitamin C, other vitamins and amino acids. It marked its 50th year on the market in 2015 with launches in South Korea and Hong Kong. In March 2015, the new and improved *Oronamin C ROYALPOLIS* was launched.



## 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.

The Otsuka Group operates its soy-related business in 11 markets worldwide, based on the concept of “Soylution,” which sees soy as a solution to various health and environmental issues. As new items in the *SOYJOY* baked soy bar range, the Group relaunched Strawberry and Blueberry in March 2015, followed in September 2015 by the relaunch of Raisin, Apple and Hawthorn Berry in Japan. Operations are gradually deploying overseas as well.

Sales of *EQUELLE*, a food product containing equol to support women’s health, have progressed steadily, reflecting the Group’s efforts to provide information with a focus on the relationship between equol and physical and emotional changes in women.



## SOYJOY

A new type of nutrition bar made using only soybean dough (wheat-free) and various other ingredients. In 2015, five improved products were released. In April 2016, *SOYJOY Crispy* was released, a soy bar for eating on the go with the light and crunchy texture of puffed soy. It is available in the three flavors of plain, mixed berry and golden berry.



## EQUELLE

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

In the cosmetics business, the Group launched new products in Japan in the *UL·OS* men's skincare brand, *UL·OS Adult Body Sheet* and *UL·OS Adult Facial Sheet* in March 2015, followed by *UL·OS Medicated Skin Whitening*, a new pen-type skin treatment that inhibits dark spots and freckles, in August 2015. Sales of the new products have been growing steadily.

Sales of the women's skincare brand *InnerSignal* increased year on year as a result of new customers and an expanded base of loyal users.



### UL·OS

This total body skin care brand for middle-aged men is based on Otsuka's unique cosmetics concept for skin health.



### 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.

\* adenosine monophosphate DT

Sales volume for the oral rehydration solution *OS-1* increased year on year due to greater awareness of the product. This reflected focused activities targeting medical personnel and healthcare professionals to encourage recommendation to patients, the product's mention in the Japanese Association for Acute Medicine's heat stroke medical treatment guideline, support activities to the Hidden Dehydration Committee and active sales promotion efforts such as television commercials and sampling.

Sales volume for the vitamin tonic *Tiovita* declined year on year, due mainly to the shrinking market for nutrient tonics and the impact of rival products.

Sales of *Oronine H Ointment* increased year on year. In Japan, this was supported by efforts to promote the benefits of a new laminated tube product launched in August 2015.



### OS-1

A rehydration drink for balancing electrolytes and glucose that is based on the approach behind the oral rehydration therapy advocated by the World Health Organization (WHO). This is a drink for patients suited for supplementing and maintaining hydration and electrolytes in people with light to moderate dehydration.



### Tiovita Drink (Designated quasi-drug)

A long-selling product that celebrates its 52nd anniversary in 2016. This vitamin health drink contains Vitamin B<sub>1</sub> and other B-group vitamins to help relieve physical exhaustion, as well as the active ingredient taurine and the digestive aid carnitine chloride.



### Oronine H Ointment

An ointment for the treatment of skin ailments and injuries, formulated with chlorhexidine gluconate. This long-selling brand has 12 effects and efficacies including acne, cuts, moderate burns, chapped skin, frostbite and cracked skin.



### Gerblé

A brand of health products originating in the south of France and featuring good nutrition and natural ingredients such as wheat germ. Since its foundation in 1928, Gerblé has been a much-loved brand of health products.



### Kenja no Shokutaku Double Support

This Japanese government-approved Food for Specified Health Use has the double function of suppressing absorption of both sugars and lipids. The product is a powder of digestion-resistant dextrin that dissolves instantly in any beverage, making it easy for consumers to take in meals at home or dining out. It comes in single-use stick-type packets for easy-to-carry convenience.



### Solmack Digestive Drink Plus (Designated quasi-drug)

Alleviates symptoms such as upset stomach associated with excessive eating or drinking. This drink contains selected natural ingredients with bitter and aromatic properties to improve stomach function.

## Highlight

### Seven Products from the *Nature Made* and *OMUGI SEIKATSU* brands Improved for More Nutrition and Newly Released as Foods with Function Claims

Foods with Function Claims are foods labeled with nutrient function claims based on scientific evidence. The producer takes responsibility for the claims and notifies Japan's Consumer Affairs Agency. The Food with Function Claims system was established in Japan in April 2015 to increase the number of products with packaging clearly labeled with the functions they offer to consumers, thereby enabling consumers to make decisions based on accurate product information.

As a corporate group closely involved with healthcare, the Otsuka Group utilizes the expertise it has built up in the pharmaceutical business to develop health products based on scientific evidence to help maintain and enhance health on a daily basis. With the launch of the new Food with Function Claims system, Otsuka hopes to provide customers with even more opportunities to choose safe, appropriate products based on clear, simple labeling.

Otsuka aspires to help all people, regardless of age and gender, to enjoy healthier lives, and to improve healthy longevity, as well. Otsuka will continue to work to provide customers with even better products based on scientific evidence.



#### *Nature Made*

*Nature Made* is a brand specializing in supplements that was launched in 1972 by Pharmavite, a company established in California in 1971. *Nature Made* supplements are free of food coloring and preservatives, and are subject to rigorous quality standards covering every step from the procurement of raw materials to quality inspections. The products are manufactured to meet Good Manufacturing Practices in the U.S. and other standards in the countries and regions in which they are sold. Currently, they are sold in nine countries and regions, and all products for the Japanese market are manufactured on dedicated production lines.

Five products in the *Nature Made* line have been improved and re-released as Foods with Function Claims: *Lutein*, *Astaxanthin*, *Fish Oil Pearl*, *Super Fish Oil* and *Ginkgo Biloba* (the first Food with Function Claims in the field of cognitive function). The release of these Foods with Function Claims makes it easier for customers to select products that help them achieve their goals. Going forward, *Nature Made* products are poised to make even greater contributions to better health.

Food with Function Claims	<i>Nature Made Lutein</i>	<i>Nature Made Astaxanthin</i>	<i>Nature Made Ginkgo Biloba</i>	<i>Nature Made Fish Oil Pearl</i>	<i>Nature Made Super Fish Oil Pearl</i>
Granted label	This product contains Lutein. Lutein is reported to support contrast sensitivity in the eyes (the eye's ability to distinguish increments of light and dark).	This product contains Astaxanthin. Astaxanthin is reported to support the eye's ability to focus on objects at different distances.	This product contains flavonoid glycosides and terpene lactones extracted from Ginkgo Biloba. Ginkgo Biloba flavonoid glycosides and terpene lactones have been reported to improve certain aspects of cognitive function (perception and recall of perceived objects).	This product contains EPA and DHA. EPA and DHA have been reported to inhibit the elevation of neutral fats in the bloodstream.	
Ingredients associated with function	Lutein	Astaxanthin	Ginkgo Biloba flavonoid glycosides, Ginkgo Biloba terpene lactones	EPA, DHA	

#### *OMUGI SEIKATSU*

The *OMUGI SEIKATSU* line, launched in 2013, was developed with a focus on barley beta-glucans, found in high levels in barley and rich in soluble fiber. Two products in this line, *Omugi Gohan* and *Omugi Gohan Japanese-Style*, have now been upgraded and released as Foods with Function Claims. These products are approved to claim that they may help control absorption of glucose, reduce blood cholesterol and balance the intestinal environment. They are the first products in rice form submitted and approved in the Foods with Function Claims system.

Food with Function Claims	<i>OMUGI SEIKATSU Omugi Gohan</i>	<i>OMUGI SEIKATSU Omugi Gohan Japanese-Style</i>
Granted label	This product contains barley beta-glucans (dietary fiber). Barley beta-glucans have been reported to be effective in controlling absorption of glucose, reducing blood cholesterol in individuals with elevated cholesterol levels and balancing the intestinal environment.	
Ingredients associated with function	Barley beta-glucans	



# Global Expansion

The global expansion of the nutraceutical business began with Asian sales of *Pocari Sweat* and now features worldwide sales of *Nature Made* by our U.S. subsidiary Pharmavite and European sales of health and functional foods by Nutrition & Santé of France.

The Otsuka Group is convinced that products developed based on scientific evidence help to bridge differences in language, culture and customs and can earn broad appeal among people all around the world. Otsuka aspires to contribute to the health of people all over the world with innovative products.



## Asia

Following the release of *Pocari Sweat* in 1982 in Hong Kong and Taiwan, the Otsuka Group has expanded the sales area of the drink, which is now produced outside Japan in China, South Korea, Taiwan and Indonesia. As of 2015, *Pocari Sweat* is sold in 20 countries and regions. In fiscal 2015, sales volume in Indonesia declined due to the impact of competing products and other factors, but in China sales volume increased due to efforts to educate consumers and enhance product value.

*Oronamin C Drink* was introduced to markets outside Japan via sales agents in 1985, and was launched in South Korea and Hong Kong in February and May 2015, respectively.

*SOYJOY*, developed under the “Soylution” concept, has provided new ways to enjoy soybeans ever since it was first released in Japan, the U.S. and China in 2006. *SOYJOY* products are tailored to the culture of the target country and region, but sometimes regional products go global. One new flavor originating in China, for example, is now marketed worldwide.

Otsuka Pharmaceutical’s first product launch outside Japan in its cosmetics business was *UL·OS*, launched in South Korea in March 2012. Sales have steadily increased, thanks to successful efforts to strengthen the brand while integrating local culture and customs.

## Highlight

### *Pocari Sweat* Now Sold in Twenty Countries and Regions



After *Pocari Sweat*’s debut in 1980 in Japan, the Otsuka Group began marketing it outside Japan in earnest in 1982, with a focus on Southeast Asia. Most recently, in 2015, the product was introduced to the market in East Timor, Myanmar and Cambodia, all of which have seen steady economic growth. The Group attributes the broad name recognition of *Pocari Sweat* outside Japan to promotional activities that convey the importance of rehydrating and replenishing electrolytes with an approach tailored to each country’s culture and lifestyle. In Indonesia, road-side educational activities have led to the widespread recognition of *Pocari Sweat* as a drink essential for rehydration. *Pocari Sweat Ion Water*, a refreshing spin on the original drink with a light sweetness, was launched in 2013 in Japan, and then in Taiwan in 2014, getting started on its global expansion. Focusing on the concept of a beverage to support the body when sweating, Otsuka Pharmaceutical will accelerate the global expansion of *Pocari Sweat* and continue to communicate the importance of rehydration to people all over the world.

### *Oronamin C Drink* Now Sold in Nine Countries and Regions

*Oronamin C Drink* is a carbonated nutritional drink that is a convenient, delicious source of Vitamin C. Even now, over 50 years since it was launched in 1965, this drink is well-loved by many people. Since 1985, the drink has been provided via agents in six countries in the Middle East. In the UAE especially, it has gained a reputation as a national drink. In February 2015, the Otsuka Group began manufacturing and selling the drink in South Korea, and launched it in Hong Kong in May 2015. Now available in nine countries and regions, the Otsuka Group is working to strengthen this global brand leveraging the “full of vitality” product concept.



### *Kenja no Shokutaku* Launched in Hong Kong

*Kenja no Shokutaku* Double Support, a Japanese government-approved Food for Specified Health Use has the double function of suppressing absorption of both sugars and lipids. It was first released outside Japan in April 2015 in Hong Kong. The restaurant industry is quite advanced in Hong Kong, and while it is one of the world’s most important areas for foods that promote beauty and longevity, the market for diet foods is also expanding. Otsuka will play up the distinct features of this product that make it great for use in a wide range of culinary scenes and focus on further product development.



## U.S.

The high quality of the products under the *Nature Made* brand, produced and marketed by Pharmavite, ensure their broad popularity in the U.S., a country that has pioneered the use of vitamins. With the growing supplement market, *Nature Made* sales increased over the previous year in fiscal 2015. With FoodState joining the Group in 2014, the company gained new access to the natural and specialty channel and practitioner channel. Sales of the products *MegaFood* and *INNATE*, supplements derived from plants, are rising steadily. Utilizing expertise developed in the U.S., where self-medication is quite common, the Otsuka Group will continue to expand its supplement business in the future.



### Pharmavite LLC

Pharmavite produces and markets *Nature Made* vitamin supplements and *SOYJOY* bars. *Nature Made* has been the best-selling vitamin supplement\* in U.S. stores for nine consecutive years since 2007.



### FoodState, Inc.

FoodState owns a proprietary technology called the Slo-Food Process™, which is used to effectively extract nutrients from fresh vegetables and fruits bought from contracted farms. The process dehydrates and condenses the foods while retaining the nutrients so that supplements can be developed with minimum synthetic ingredients and additives. FoodState will further develop *MegaFood* and *INNATE*, two supplements derived from natural foods using these technologies. This business is expected to benefit from its unique marketing channels targeting natural food stores, supplement specialty stores and medical practitioners.

\* Pharmavite calculation based in part on data reported by Nielsen through its Scantrack® service for the Total Vitamins Category in dollar and unit sales, for the 52-week periods ending 12/27/2008 in the U.S. Food Drug Mass channels; and for the 52-week periods ending 12/26/2009 through 12/19/2015 in the U.S. xAOC channels. © 2016 The Nielsen Company

## Europe

Nutrition & Santé (N&S), which operates primarily in Europe, experienced growth in 2015 driven by gluten-free products marketed under the *Gerblé* brand of nutrition and health foods. Organic foods and bean-based products also grew steadily. In October 2015, N&S acquired BIOCENTURY, a leading Spanish health and functional foods company. In 2014, Jasmine, a company with a sales network in Brazil, was added to the Group, heralding a new entry into the South American market.



### Nutrition & Santé SAS

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

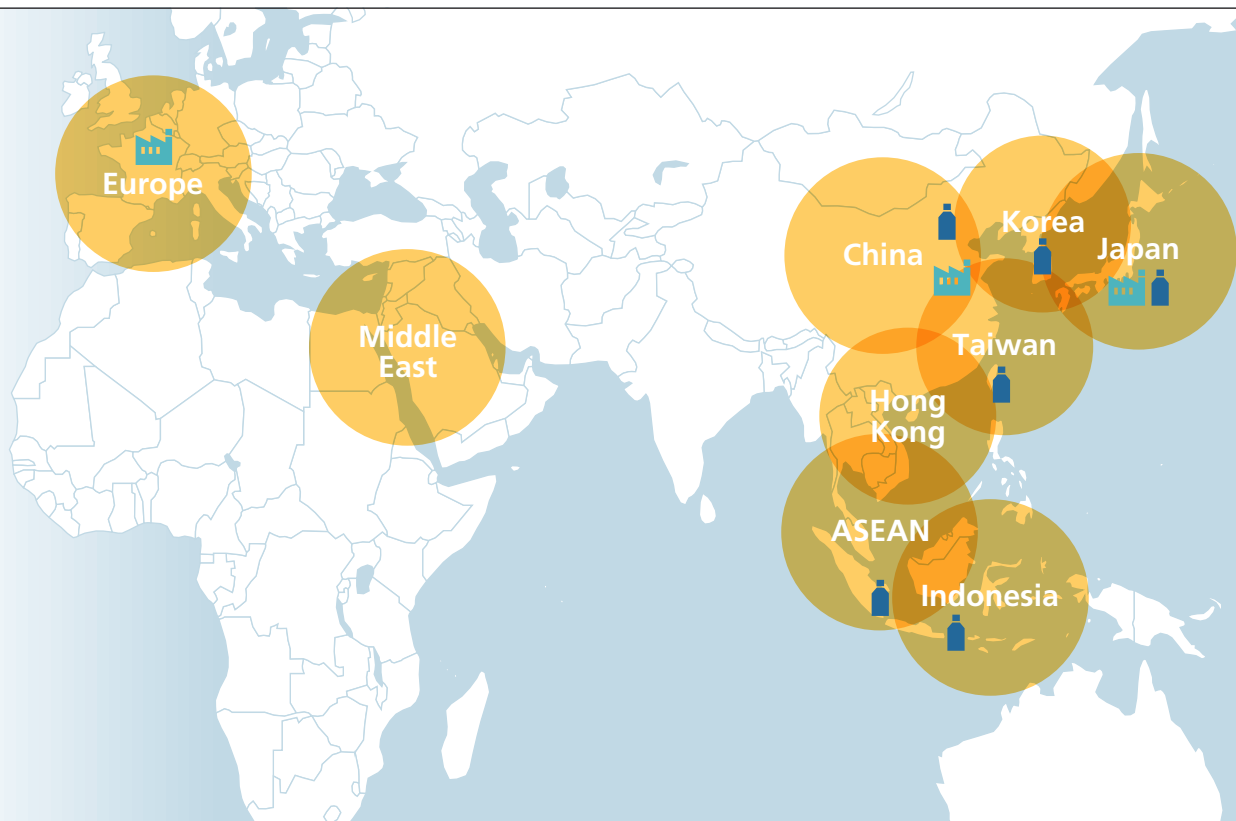
## Highlight

### Nutrition & Santé Acquires BIOCENTURY, a Leading Spanish Health and Functional Foods Company



N&S concluded an agreement in October 2015 to acquire BIOCENTURY, a leading Spanish health and functional foods company.

BIOCENTURY was established in 1980 to put into practice the philosophy that “eating well helps people to improve their health and beauty.” In the 35 years since then, the company has expanded sales of health and slimming foods in Spain. In 1992, BIOCENTURY launched the first meal-replacement cereal bars in Spain, followed by a line of rice cake products offering breakfast alternatives, both of which have achieved broad popularity among consumers in Spain. This acquisition will make N&S the top purveyor of slimming foods in Spain’s supermarkets. BIOCENTURY’s plant located at Quart, which is near Girona close to the Spanish-French border, has proprietary production facilities, including technologies for producing puffed foods. The acquisition of this plant will enhance N&S’s own production capacity and help accelerate its European business expansion plans.



 **Japan**



**Europe**

**2009**  
Nutrition & Santé joined the Otsuka Group



**2011**  
Launched SOYJOY  
(France, Spain, Belgium, Italy)



**Middle East**

**Countries where Pocari Sweat is sold and years launched**

- Bahrain, Saudi Arabia, Oman (1983)
- U.A.E. (1984)
- Kuwait (1986)
- Qatar (2003)
- Egypt (2008)

**1985** Launched *Oronamin C Drink*  
(U.A.E., Kuwait, Bahrain, Oman, Saudi Arabia, Qatar)



 **South Korea**

- 1987** Launched *Pocari Sweat*
- 2007** Launched *SOYJOY*
- 2015** Launched *Oronamin C Drink*

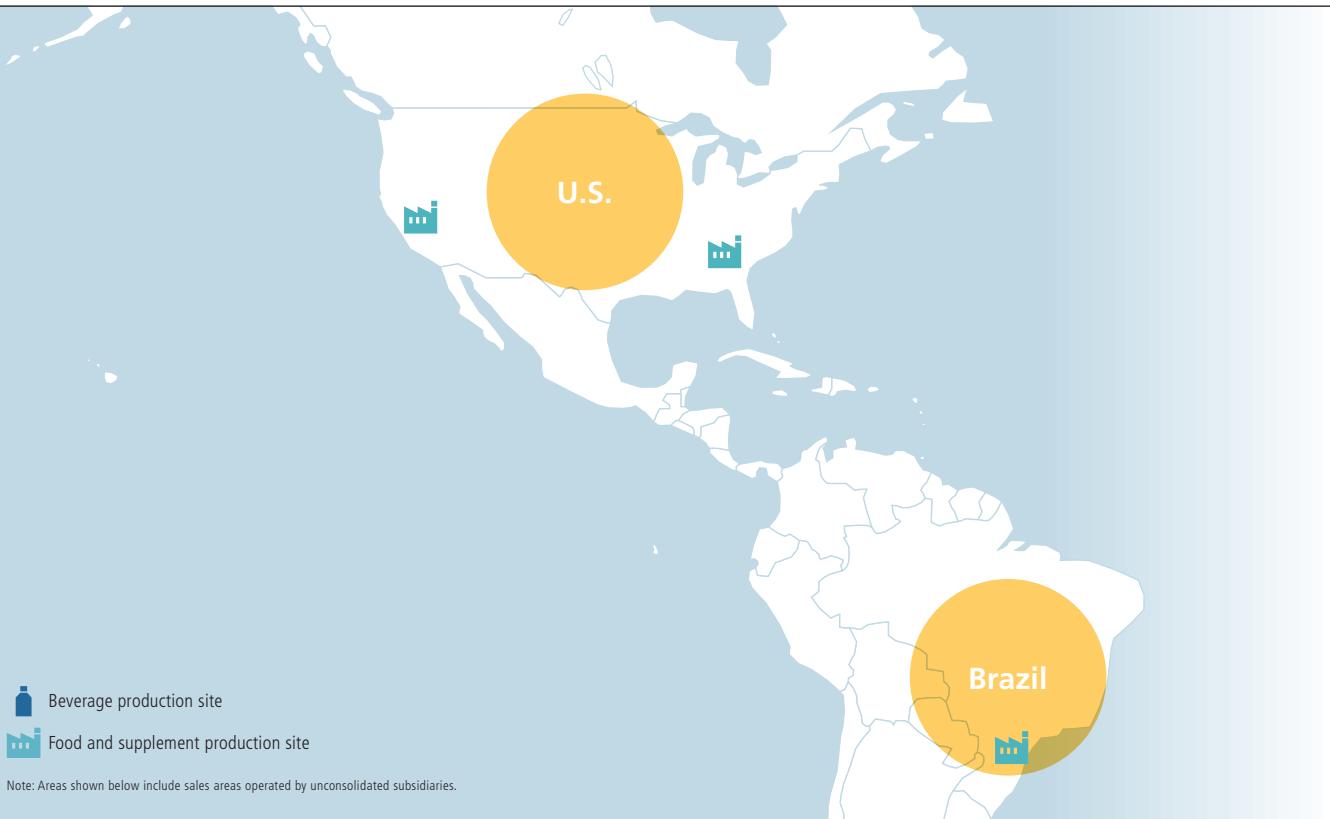


 **China**

- 2003** Launched *Pocari Sweat*
- 2006** Launched *SOYJOY*







**Taiwan**

- 1982** Launched *Pocari Sweat*
- 2007** Launched *SOYJOY*
- 2014** Launched *Pocari Sweat Ion Water*



**Hong Kong**

- 1982** Launched *Pocari Sweat*
- 2007** Launched *SOYJOY*
- 2015** Launched *Kenja no Shokutaku* and *Oronamin C*
- 2016** Launched *Tiovita 3000*



**Indonesia**

- 1989** Launched *Pocari Sweat*
- 2007** Launched *SOYJOY*
- 2015** Launched *Pocari Sweat IONESSENCE*



**U.S.**

- 1989** Pharmavite joined the Otsuka Group
- 2007** Launched *SOYJOY*
- 2014** FoodState joined the Otsuka Group



**ASEAN**

**Countries where Pocari Sweat is sold and years launched**

- Singapore (1983)
- Thailand (1998)
- Malaysia (1999)
- Philippines (2007)
- Vietnam (2012)
- Myanmar, East Timor, Cambodia (2015)

- 2008** Launched *SOYJOY* in Singapore



**Brazil**

- 2014** Jasmine joined the Otsuka Group



## Segment Overview

The Otsuka Group's Consumer Products segment focuses on delivering familiar food and beverages that are delicious, safe, reassuring, and healthy.



# Consumer Products Business

The Otsuka Group's food products business has been going strong since the 1968 launch of *Bon Curry*, the world's first commercially available food product in a retort pouch. Then came *Mannan Hikari*, *My Size*, and many other products that were all ahead of their time. In the *My Size* line, which is based on the concept of "a meal that's just the right size," the Group now markets the *My Size: line! Plus* series in pharmacies across Japan. This is the first series for people who are worried about their intake of salt and protein. Otsuka Foods has also launched new products under the brand *Shizen Shokkan*, which draws on the concept of using delicious and fun ingredient textures to make the body happy.

In the beverages business, Otsuka Foods offers a product line suited to a variety of lifestyles and tastes. These include *Berry Match*, a drink with the flavor of five mixed berries, part of the *Match* lineup, a carbonated vitamin drink range nearing its 20th anniversary. The company also markets the longtime best-seller *Sinvino JAVA Tea Straight* and *CRYSTAL GEYSER*, a soft mineral water bottled directly from a spring at the base of Mt. Shasta in the U.S.



## Highlight

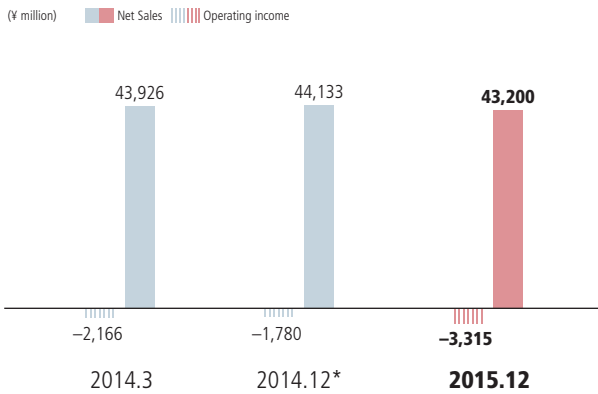
### Bon Curry's Great Taste

*Bon Curry* is a curry packaged in a retort pouch made with no preservatives or artificial coloring, so consumers can have peace of mind. Some products, such as *Bon Curry Neo* and *The Bon Curry*, only use vegetables grown in Japan. In 2016, Otsuka Foods began to use Japan-grown vegetables for its ingredients in *Bon Curry*, the standard product in this retort pouch lineup, further enhancing the taste.

In February 2016, Otsuka Foods released *Bon Curry for Children*, a curry especially for children, developed based on the opinions of mothers who are raising children today. This mild and slightly sweet chicken curry uses 10 types of Japan-grown vegetables and provides the nutrients that children tend to lack. As a pioneer in retort-packaged foods, Otsuka Foods will continue to adapt *Bon Curry* to the changing times.



# 2015 Performance



Sales of the carbonated vitamin drink *Match* declined, but the Group is revitalizing this brand using proactive marketing strategies and activities. Sales volume was solid for the mineral water lineup, based on *Crystal Geyser*. Efforts to raise the brand value of *Bon Curry* paid off with growth in sales volume over the previous year. Overall in fiscal 2015 net sales in the consumer products business fell 2.1% from the previous year to ¥43,200 million and the segment posted a ¥3,315 million operating loss. The Otsuka Group is currently working to improve the revenue structure of this business by reforming the marketing system with a full overhaul of marketing strategy and sales promotion activities.

\* As a result of the adoption of a new fiscal year end, the fiscal year ended December 2014 was an irregular nine-month period. For reference, we have included consolidated profit/loss figures (not audited) for all consolidated companies for the period from January 1, 2014 to December 31, 2014.  
Note: Intersegment sales are included.

## Operating Companies



### Otsuka Foods Co., Ltd.

Otsuka Foods was established in 1955 with the philosophy that companies start with people and food comes from the heart. All employees work to create delicious tastes and provide safety, peace of mind and good health. Development starts with the goal of bringing this food from the heart to the people the company values most. Otsuka Foods manufactures, sells and imports food and beverages.



### ALMA S.A. (Orne, France) \* Affiliated company

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



### Crystal Geyser Water Company

(Calistoga, California)



The Crystal Geyser Water Company was established in 1977 as a manufacturing plant for sparkling mineral water. Its flavor development has made this company a pioneer in the sparkling mineral water segment. Other products include Tejava Premium Iced Tea (sold as *JAVA Tea Straight* in Japan). In the 1990s, this company joined the Otsuka America Inc.



### 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 team to provide safe, reliable, and high-quality products.

## Segment Overview

The Otsuka Group's Other segment operates multiple businesses such as chemicals, transportation, warehousing, and electronic equipment.



# Other Business

## Chemicals

In the Chemicals business, the Otsuka Group constantly pursues technological innovation, aiming to create products based on real materials that enrich the lives of consumers. The hydrazine business, the inorganic materials and composite materials business, and the medical intermediate business take the central role in providing products globally to the automotive, electrical and electronic, housing-related and pharmaceutical fields. With a focus on organic and inorganic synthetic technology, the R&D division of this business researches and develops new products that make the most of its proprietary technology and pursues research and development in completely new, next-generation fields.

### Operating Companies

#### P.T. Lautan Otsuka Chemical

(Jakarta, Indonesia)

Lautan Otsuka Chemical produces and markets foaming agents and is currently working to develop environmentally friendly inorganic foaming agents for use in automobiles, pallets, and building materials. The company marked its 25th anniversary in 2014.



#### Zhangjiagang Otsuka Chemical Co., Ltd.

(Zhangjiagang, China)

This company produces and markets potassium titanate (*TERRACESS*), a frictional material used mainly in brake pads, as well as special engineering plastic compounds (*POTICON*). The company is also involved in research and development and has been certified as a high-tech company by the Jiangsu Science and Technology Department. Zhangjiagang Otsuka Chemical marked its 10th anniversary in 2014.



## Highlight

### The Otsuka Group Completes Plant in North America to Manufacture Materials for Auto Brakes, Shifting to Three-Hub Production System Based in Japan, China and North America

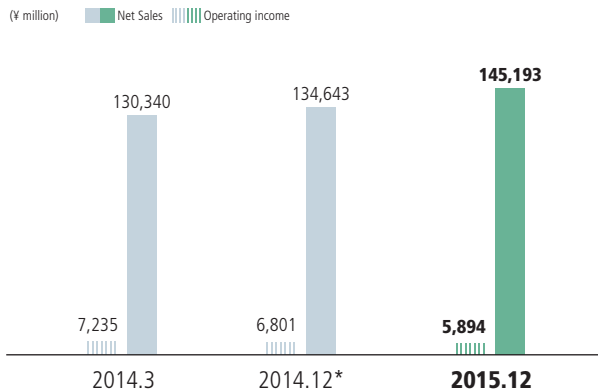
Otsuka Chemical America Inc., established in February 2014 by Otsuka Chemical, completed construction in July 2015 of a plant to manufacture *TERRACESS*, a product available in magnesium potassium titanate, lithium potassium titanate, and several other titanates. This plant will be the company's third manufacturing base, joining plants in Japan and China. Demand for *TERRACESS*, a material used in automotive brake pads, has been growing. The completion of this plant will enable the company to sell *TERRACESS* in the North and South American markets, particularly in the U.S., which has a robust market for new automobiles and is home to many brake pad development facilities. In addition, Otsuka Chemical America Inc. will function as Otsuka Chemical's regional headquarters in the U.S.



#### About *TERRACESS*

*TERRACESS* is a titanate material that has been developed in a flaky (platelet) microparticle form. This material is used in applications such as micro-reinforcement and friction. For over 30 years, Otsuka Chemical has researched and developed technology to control the shape of this titanate material, and has successfully produced a wide variety of different shapes and compositions. By using *TERRACESS*, customers can minimize brake squeal and variability in wear between pads, thereby enabling long-term stable brake performance.

## 2015 Performance



In the specialty chemical business, sales of *TERPLUS*, pigment dispersing agents used in color filters and inkjets, increased compared with the same period of the previous year due to increases in the number of new users and sales to existing users. However, sales volume of hydrazine hydrate declined. As a result, sales overall in the specialty chemical business were steady compared with the same period of the previous year. In the fine chemical business, sales increased year on year due to higher unit sales prices for pharmaceutical intermediates overseas and forex factors. In the transportation and warehousing business, there were increases in new external customers and in new deals in the overseas distribution business. As a result, sales increased compared with the same period of the previous year. Sales in the direct sales support business also increased year on year due to growth in the volume of orders handled. As a result, net sales in the other segment for the fiscal year ended December 31, 2015 totaled ¥145,193 million (up 7.8% year on year), with operating income of ¥5,894 million (down 13.3%).

\* As a result of the adoption of a new fiscal year end, the fiscal year ended December 2014 was an irregular nine-month period. For reference, we have included consolidated profit/loss figures (not audited) for all consolidated companies for the period from January 1, 2014 to December 31, 2014.  
Note: Intersegment sales are included.

## Transportation and Warehousing

Otsuka Warehouse, which distributes products to market for the Otsuka Group and other firms, has shifted from its previous warehouse management approach, which was based on "instinct and experience," to an original data-driven "ID Warehouse and ID Transport" concept that leverages data and IT. Tablet terminals have been introduced at its distribution centers to facilitate smooth navigation of the processes involved in tracking the arrival of products at the warehouse, carrying out inventory management, and facilitating the shipping of products to market. This approach has raised the efficiency of operations in the logistics center. Otsuka Warehouse has also built a truck allocation system called ID Transport to mitigate driver shortages in the logistics industry. This system received the fiscal 2015 Logistics Award from the Japan Institute of Logistics Systems, the most coveted award in the logistics industry.

### Highlight

#### Pharmaceutical Distribution Center Completed; Operation of BCP\*-Compliant Center to Strengthen Stable Supply System for Pharmaceutical Products

In October 2015, Otsuka Warehouse completed its West Japan Logistics Center, a logistics center exclusively for pharmaceutical products located in the north of Kobe in Hyogo Prefecture. This new center is ideal for BCP because it is located on low ground where the risk of earthquakes is low, it is equipped with its own power source, and it was built with an anti-seismic structure. In addition, the facility was built to raise the quality of pharmaceutical products by introducing new features such as full-scale security management, automatic temperature management systems and insect prevention equipment. Moreover, the company has shifted from its previous warehouse management approach, which was based on "instinct and experience," to an "ID Warehouse" concept, resulting in warehouses that can be managed by anyone. As a logistics company for manufacturers of pharmaceuticals that help people lead richer and healthier lives, Otsuka Warehouse will take the opportunity presented by the completion and launch of this center to advocate for the creation of joint platforms. The company will continue to carry out joint distribution with manufacturers and improve the efficiency of distribution while also developing platforms that can contribute to society.



\* BCP: business continuity plan

## 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.

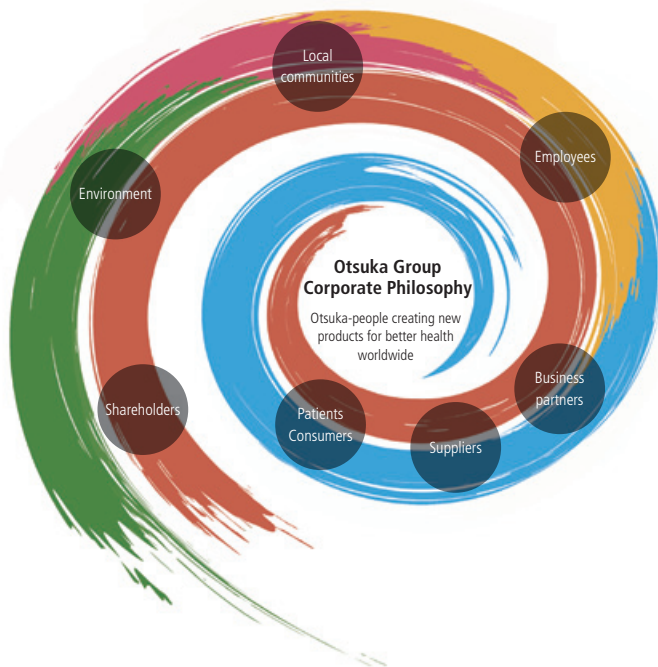
## The Otsuka Group's Approach to CSR

### Otsuka's Efforts to Fulfill Social Responsibility by Creating New Products for Better Health Worldwide: Evolving with Stakeholder Engagement

Otsuka's approach to social responsibility is driven by its determination to live up to its corporate philosophy, "Otsuka-people creating new products for better health worldwide." Otsuka's specific initiatives evolve as stakeholders become engaged and increasingly involved. This is only natural, since Otsuka's business activities require the understanding, cooperation and support of many stakeholders, including local communities, suppliers, patients, and consumers. The Group contributes to society in various ways, including initiatives to benefit the local communities where it operates and protect the natural environment. These initiatives, in turn, directly and indirectly help Otsuka to improve its manufacturing and services. Delivering products and services highly valued by customers helps develop the Group's business and enhances relationships of shared trust with stakeholders.

With this approach, Otsuka aspires to create a virtuous cycle of synergies through community partnerships built on customer trust, loyalty and support. The more the Group is able to give back to society, the more goodwill it will accrue naturally.

By pursuing CSR as an integral part of its business, the Otsuka Group aims to continue as a valued, necessary partner for society.



### Otsuka Group CSR Vision

The Otsuka Group CSR vision draws inspiration from the forward and backward flows of the famous eddies in the Naruto Straits, near the city in Tokushima, Japan where Otsuka was founded. In a way analogous to these two-way currents, the Otsuka Group contributes profits back to society in one direction, while in the other direction it pursues commercial activities rooted in its corporate philosophy that reinforce social goodwill.



### Five Areas of Otsuka Group CSR

The Otsuka Group has determined five focus areas for its unique approach to CSR: health, environment, quality, culture, and employees. These five areas resonate with Otsuka's business operations, positioning the Group to make impactful social contributions.

<p><b>Health</b></p> <p>As a comprehensive healthcare company, the Otsuka Group is focused on developing innovative products and seeking ways to maintain and promote better health for all.</p>	<p><b>Environment</b></p> <p>Our lives, communities and business activities are inextricably linked to the environment. Otsuka Group embraces its responsibility to care for the environment and pursue sustainability at every stage, from the manufacturing of products to their use.</p>	<p><b>Quality</b></p> <p>Otsuka's approach to product quality extends beyond safety and security in manufacturing. Striving also to enhance the quality of its social initiatives, the Group is focused on a broad range of activities, from information transparency and disclosure, to collaboration with business partners, to respect for local communities, and ensuring compliance with regulations.</p>	<p><b>Culture</b></p> <p>Otsuka respects local communities and their traditional cultures. The Group contributes to community development and in particular to the education of children, who represent the future of their communities, through community exchanges, partnerships, and support for education.</p>	<p><b>Employees</b></p> <p>The spirit of <i>Sozosei</i> (creativity) instilled in every employee of the Otsuka Group stems from their desire to emulate the corporate philosophy. The Group fosters a corporate culture that encourages a diverse workforce to break out of the conventional, broaden their perspectives, and never stop in their personal development. This collective creativity, in turn, enables the Group to continue developing innovative products that enrich society.</p>
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More information on Otsuka Group CSR initiatives is available online at:

Otsuka Group CSR portal

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



# Environment

True to the Otsuka Group Environmental Policy, the Otsuka Group works to protect the global environment via a well-established system for implementing environmental initiatives around the world. The Group states seven elements as activity guidelines. Under these guidelines, the Group actively pursues initiatives such as eco-friendly products to reduce environmental impact throughout the product life cycle; curbing CO<sub>2</sub> emissions by promoting energy conservation and increasing productivity; and striving to achieve zero waste for final disposal through a 3R (reduce, reuse, and recycle) program. The Group's production facilities also implement their own activities focused on protecting the natural environment and building harmonious relationships with the local community.

## Otsuka Group Environmental Policy

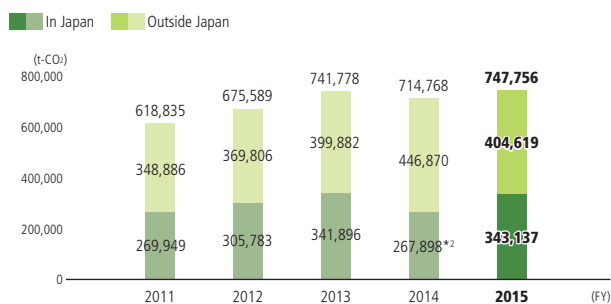
As a global healthcare company and a responsible corporate citizen, the Otsuka Group will always take account of the global environment when it pursues its business activities. The Group will work on environmental issues with its trademark qualities of independence, proactiveness, and creativity.

## Guidelines

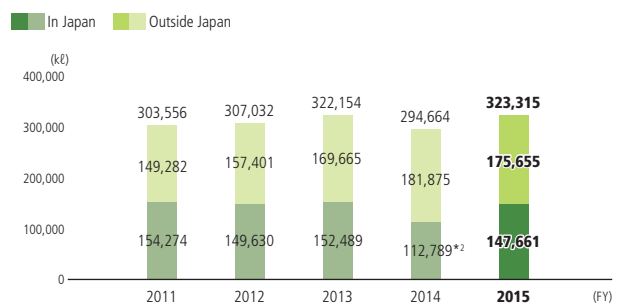
- 1 Provide products and services that are friendly to the environment
- 2 Contribute to a low-carbon society
- 3 Contribute to a sound material-cycle society
- 4 Conserve biodiversity
- 5 Ensure compliance
- 6 Actively engage in social initiatives
- 7 Enhance risk management

## Environmental Performance Data \*1

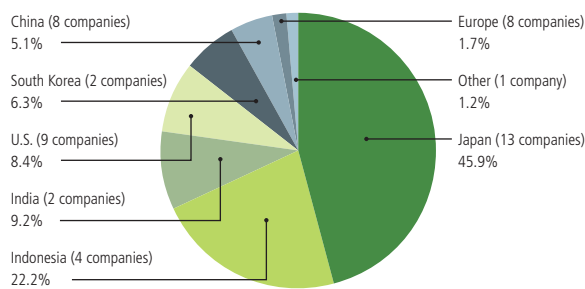
### Total CO<sub>2</sub> Emissions (Energy-related)



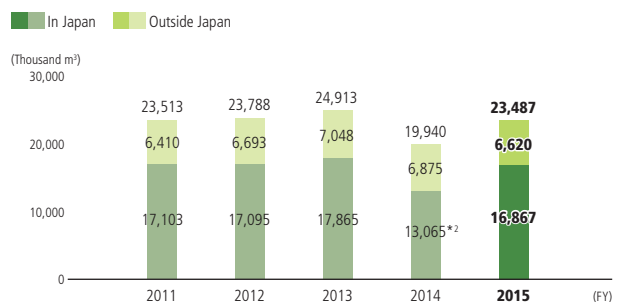
### Energy Usage (Crude-oil equivalent)



### Otsuka Group CO<sub>2</sub> Emissions by Country in FY2015



### Water Usage by Group Companies



\*1 Figures indicate total values for 13 companies in Japan and 34 Group companies outside of Japan (consolidated companies which have a production site). \*2 Results are for the nine months Apr–Dec

## Creating Biotopes and Building Harmonious Relationships with wildlife and the Local Community

A manufacturer of pharmaceuticals and soy products, Otsuka Pharmaceutical's Tokushima Itano Factory focuses on building harmonious relationships with the natural environment as its concert. Working with the original landscape, the factory has planted native trees on the grounds and has worked with Tokushima Prefecture officials and others to protect and breed cyprinid fish, listed as endangered species in its biotope pond, utilizing cooling water from the plant.



## Health

The Otsuka Group is passionate about people's health. We strive to create groundbreaking new products that save or extend lives and improve the quality of life of people with unmet medical needs. In pharmaceuticals, the Otsuka Group is focused on research and development to create innovative drugs, particularly in central nervous system and oncologic diseases.

The Group applies the same scientific rigor and experience from its pharmaceuticals business to the development of functional foods and beverages. The Group leverages its experience to educate on prevention of heat disorders, in medical settings, schools and offices. In addition, to improve the public's information about health, information related to food, nutrition, and diet is widely disseminated by the Group.

### Otsuka Health Comic Library

The Otsuka Group has been publishing the Otsuka Health Comic Library since 1989 as an activity to contribute to better children's health. One volume is issued each year, and a total of 26 volumes (including special volumes) containing a total of 259 stories have thus far been donated to elementary, special needs, and other schools throughout Japan.

The books are used by children for reading material and self-study, and also as teaching material in student committee activities. In August 2015, the city of Kawaguchi in Saitama Prefecture held the First Otsuka Health Comic Library Workshop for Health Education. The workshop was attended by approximately 100 people, including elementary school nurses and other school faculty and members of the Committee to Promote Better Dietary Habits.



## Quality

The Otsuka Group's socially responsible approach to quality extends beyond the quality and safety of its products.

In order to ensure stability in its business activities and sustainable corporate growth, the Otsuka Group works hard to earn the trust of all of its stakeholders. Its sound and highly transparent management structure is an essential component of these efforts. Otsuka Holdings formulated its Corporate Governance Guidelines in accordance with Japan's Corporate Governance Code for companies listed on the Tokyo Stock Exchange. The guidelines set out the Group's basic approach to corporate governance in line with the Group philosophy and taking account of the status of business operations. The Group is absolutely committed to the five basic principles laid out in the Code: securing the rights and equal treatment of shareholders; appropriate cooperation with stakeholders other than shareholders; ensuring appropriate information disclosure and transparency; responsibilities of the board; and dialogue with shareholders.

The Otsuka Group views a corporate climate that upholds extremely high ethical standards, including compliance with laws, regulations, and bioethics, as the foundation of product quality. Established in 2014, the Otsuka Group Global Code of Business Ethics is integrated into compliance training sessions at all Otsuka Group companies to ensure that employees have a thorough understanding of what is expected of them.

In order to enhance its whistleblowing system, Otsuka Holdings established a point of contact at two external law firms in November 2015. Major Otsuka Group companies have also established independent external points of contact.

### Otsuka Pharmaceutical: Asia and Middle East Compliance Officer Meeting

As awareness of compliance grows around the world, Otsuka Pharmaceutical has appointed compliance officers in Asia and the Middle East and is actively working to strengthen compliance in these regions by enacting local regulations and conducting compliance training sessions.

In May 2015, a meeting of compliance officers from relevant companies in Asia and the Middle East was held in Hong Kong. The two-day meeting featured lively discussions.





## Culture

The Otsuka Group provides various support activities rooted in local communities, and its donation and volunteer activities include the provision of natural disaster relief around the world and of medical support to refugees fleeing from regional conflicts.

In Japan, the Otsuka Group leverages our expertise and knowledge to help prevent lifestyle diseases, promote activity through sports, and mitigate the effects of heat disorders. In addition, Otsuka contributes to disaster prevention through distribution of products and dissemination of health information in emergencies, in partnership with local governments.

For the local vitalization of Tokushima, Otsuka's birthplace, the Group established the Otsuka Museum of Art, a museum of ceramic board facsimiles of masterpieces from around the world, while simultaneously promoting local arts and culture. The Group is also works with local communities on cultural events and cleanup campaigns.

In addition, the Otsuka Group recognizes that today's children are tomorrow's leaders and so focuses intently on activities that enrich childhood education, such as at-school instruction by visiting employees, factory tours, and construction of libraries in Indonesia.

### Building Relationships with Local Communities in Indonesia

In Indonesia, P.T. Amerta Indah Otsuka has held *SATU HATI* ("One Heart") charity events since 2007. The profits and donations collected at these events have been used to build 28 school libraries and provide more than 120,000 books. In addition to giving tours of the company's plant and establishing a local learning center, Amerta Indah Otsuka opens the soccer field and mosque on its grounds to adults and children living in the area. The learning center focuses on children's education by holding *SATU HATI* classes once a week for elementary school students living nearby and bringing in company employees for after-school tutoring in reading, writing and math.



## Employees

The Otsuka Group understands that its employees are the driving force behind corporate growth. As part of its human resource development efforts, each Group company endeavors to ensure that they embrace diversity and provide every employee with the opportunity to make the most of their unique strengths.

The Otsuka Group has worked to promote diversity since the 1980s. It holds Women's Forums and has developed a Diversity Promotion Project, seeking to build a foundation for the promotion of more women to management positions. The Group also aims to help employees achieve a healthy work-life balance. It has built a system including on-site childcare centers and flexible working condition for employees to balance their professional and personal lives.

To retain the unique spirit that has defined Otsuka, we focus on development and training of young employees and new global leaders through a wide array of programs, including seminars to encourage multiple viewpoints, and study in the U.S. through an MBA support program.

### Percentage of female managers

	As of December 31, 2014	As of December 31, 2015
Otsuka Pharmaceutical	7.75%	8.56%
Otsuka Pharmaceutical Factory	3.54%	4.10%
Taiho Pharmaceutical	3.94%	5.23%
Otsuka Chemical	7.19%	8.15%
Otsuka Warehouse	7.59%	9.38%
Otsuka Foods	4.76%	5.14%

### Establishment Workplace Childcare

The Otsuka Group has opened three on-site childcare centers. These centers accept new enrollments each month and offer temporary childcare, care for sick children, and extended-hour care. They provide essential support for employees who are raising children while pursuing their own careers. The centers' curricula are designed to nurture creativity and an environment to encourage children to express their individuality.



## 1. Basic Approach

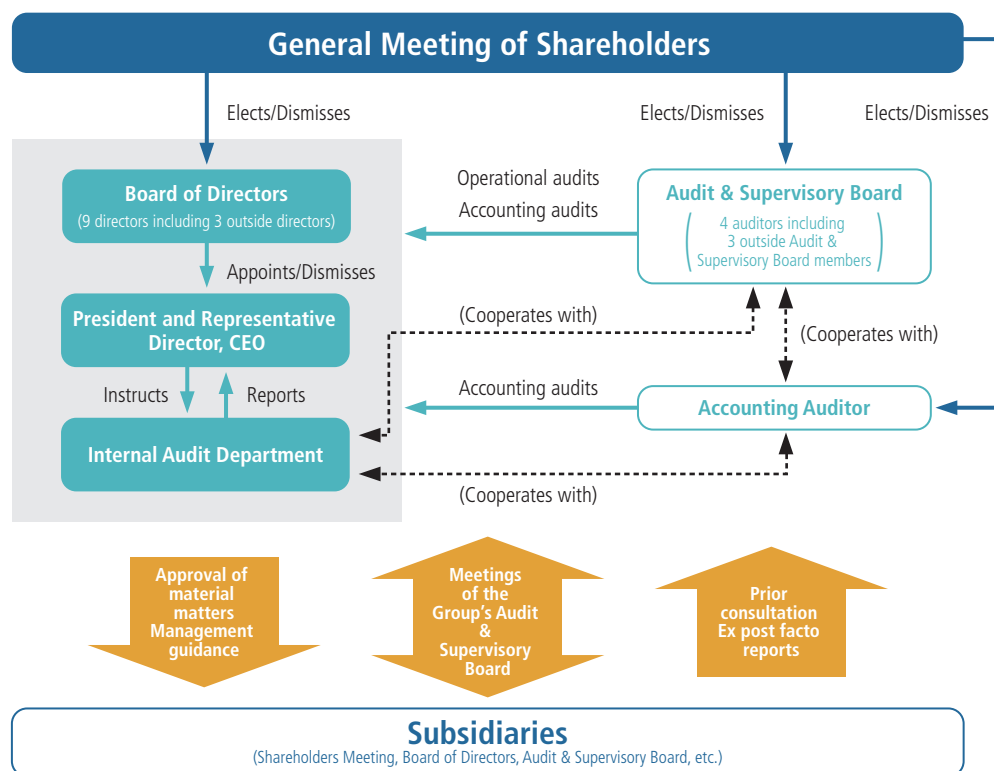
The Otsuka Group is committed to promoting sustainable increase of its corporate value over the medium- to long-term by realizing its corporate philosophy: "Otsuka-people creating new products for better health worldwide." To meet this commitment, it adopts a basic policy of making transparent, fair and timely decisions and fulfilling its corporate social responsibility by living up to the expectations of all stakeholders, including customers, business partners, employees, local communities, and shareholders, through ongoing dialogue. Otsuka Holdings articulates its basic approach to corporate governance in its Corporate Governance Guidelines.

Corporate Governance Guidelines available on Otsuka Holdings website.

<http://www.otsuka.com/en/company/governance>

## 2. Corporate Governance Structure

Below is a diagram of Otsuka Holdings' corporate governance structure. (As of end of March, 2016)



Otsuka Holdings adopts the current structure to continuously increase corporate value and maintain a highly transparent governance structure for management oversight. As part of this, the Board of Directors and the Audit & Supervisory Board, both of which include a number of outside members, work closely together to enable effective exercise of the functions of the Audit & Supervisory Board, resulting in strengthened supervisory functions for Group management.

## (1) Corporate Organization

As a company with a board of corporate auditors, Otsuka Holdings has established a Board of Directors and an Audit & Supervisory Board, and engages an accounting auditor. In order to increase the monitoring capabilities of the Audit & Supervisory Board, more than half of its members required to be outside members. This enables the Company to pursue sound business management.

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 & Supervisory Board members shall not exceed five.

## (2) Directors and the Board of Directors

In accordance with Board regulations, the Board of Directors convenes once a month and holds extraordinary meetings as necessary to make important business decisions and supervise the execution of operations. As of the date of submission of this report, there are nine directors. Information related to directors' performance of duties is stored and managed appropriately and reliably and maintained in an accessible format where needed, in accordance with the Company Documents Management Rules.

## (3) Audit & Supervisory Board Members and the Audit & Supervisory Board

Otsuka Holdings has adopted a statutory auditor system. Each Audit & Supervisory Board member attends and expresses opinions in meetings of the Board of Directors and monitors the legality and soundness of management as represented by the directors' performance of their duties, with audits by the Audit & Supervisory Board at the core of this process.

Systems have been put in place for Audit & Supervisory Board 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 & Supervisory Board members are conducted effectively. A Statutory Auditor's Office has been established to assist the duties of Audit & Supervisory Board members. It conducts the work of convening meetings of the Audit & Supervisory Board and assisting in the duties of Audit & Supervisory Board members independent of the chain of command of Board directors.

Furthermore, Audit & 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 Accounting Auditor, in an effort to improve the effectiveness of their audits.

Otsuka Holdings does not establish committees. Audit & Supervisory Board member Hiroshi Sugawara holds qualifications as a certified public accountant and has considerable expertise in financial affairs and accounting.

## (4) Outside Directors and Outside Audit & Supervisory Board Members

Otsuka Holdings has three outside directors and three outside Audit & Supervisory Board members.

The role of the outside directors is to enhance the governance function of the Board of Directors, which supervises business execution and ensures appropriate decision making, by providing effective advice from a neutral and

objective viewpoint, based on broad insights and extensive experience. When necessary, the outside directors also ascertain conditions at the Internal Control Department, while strengthening and enhancing the management oversight function through various activities in the Board of Directors.

The outside Audit & 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 & 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 Accounting Auditor, in an effort to improve the effectiveness of their audits.

The Company is satisfied that the outside directors and outside Audit & Supervisory Board members have deep insight and a wealth of experience in corporate management and maintain their independence.

Until the end of March 2013, outside director Yasuyuki Hirotoomi was Vice President and Representative Director of Resona Bank, Ltd. He currently serves as Board Director and Senior Vice President of KYOEI STEEL LTD. and Outside Director of ELECOM CO., LTD. Resona Bank is a major lender of the Group. The Otsuka Group has no business relationship with KYOEI STEEL or ELECOM. Until the end of April 2011, outside director Tadaaki Kounose was President and Representative Director of MEGMILK SNOW BRAND Co., Ltd., and an Administrative Council member 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 Otsuka Group has no transactions with the University of Miyazaki. Outside director Yukio Matsutani is Vice President of the International University of Health and Welfare. The Group has no business relationship with the International University of Health and Welfare. As of the date of submission of this report, outside Audit & Supervisory Board members Norikazu Yahagi and Hiroshi Sugawara held 18,000 and 8,000 shares, respectively, of common stock in Otsuka Holdings. Hiroshi Sugawara holds qualifications as a certified public accountant and is also an outside Audit & Supervisory Board member of Otsuka Pharmaceutical Co., Ltd., and Vice President of Will Capital Management Co., Ltd. Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings. The Group has no business relationship with Will Capital Management. Outside Audit & Supervisory Board member Yoko Wachi is an attorney at law and is an Outside Auditor at NICHIAS Corporation. The Group has no business relationship with NICHIAS Corporation.

Otsuka Holdings has appointed the outside directors Yasuyuki Hirotoomi, Tadaaki Kounose, and Yukio Matsutani, and the outside Audit & Supervisory Board members Norikazu Yahagi, Hiroshi Sugawara, and Yoko Wachi, as Independent Officers, as provided for under the rules of Tokyo Stock Exchange, Inc., with which it has registered them.

The following criteria are used for appointing outside directors and outside Audit and Supervisory Board members.

With respect to outside directors and outside Audit & Supervisory Board members, the Company has set standards for appointing talented persons who have extensive knowledge and experiences, and are able to adequately exert their ability to oversee the directors by supervising, monitoring, or auditing the latter's performance of their duties fairly and objectively from a neutral and objective viewpoint. The Company realizes that one criterion for ensuring neutrality and objectivity of outside directors and the outside Audit & Supervisory Board members is independence from management, and that an independent outside director or outside Audit & Supervisory Board members must be a person who has no conflict of interest with the general shareholders. Otsuka Holdings has established standards of independence for outside directors in order to ensure their independence in the Corporate Governance Guidelines of the Company. The Company also determines the independence of outside Audit & Supervisory Board members in accordance with the standards.

### Independence Standards for Outside Directors

The Company determines that an outside director is independent if none of the following applies to the outside director:

1. A person who is a relative within the second degree of kinship of an outside director is currently or has been in the past three fiscal years a managing director, executive officer, executive operating officer or important employee (each an "Executive") of the Company or one or more of the Company's subsidiaries.
2. A company to which an outside director belongs as an Executive has a transaction with the Otsuka Group, and the amount of such transactions in any fiscal year within the past three fiscal years exceeds 2% of consolidated net sales of either company.
3. An outside director, as a legal, accounting or tax expert or as a consultant, has received remuneration exceeding ¥10 million per fiscal year directly from the Otsuka Group (excluding remuneration as the Company's outside director) in any fiscal year within the past three years
4. The amount of donation to a non-profit organization to which an outside director belongs as an Executive from the Otsuka Group has exceeded ¥10 million in total for the past three fiscal years and such amount exceeds 2% of the income of such non-profit organization.

### (5) Internal Audit Department

The Company operates an Internal Audit Department (four members as of the date of submission of this report) 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 & Supervisory Board members. When the need for improvements is indicated, the department issues

recommendations for actions to be taken and afterward confirms the status of implementation in an effort to optimize the performance of duties. The department also shares information with Audit & Supervisory Board members and the Accounting Auditor and in other ways cooperates with them.

### (6) 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 that employees thoroughly understand operational rules. The department continuously monitors the status of operations in cooperation with the Internal Audit Department, and has established a system in which the assessment of internal controls by executives is conducted reliably.

### (7) 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.

### (8) 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 seven other certified public accountants and six other people. All of the certified public accountants who audited the Company's accounts have done so continuously for less than seven years.

## 3. 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 required for important matters in these reports. In this way, we have established a system for coordination within the Otsuka Group.

The Company and its main subsidiaries have adopted a statutory auditor system and appointed a number of Audit & Supervisory Board members, who work together to audit the directors' performance of duties and thereby enhance the effectiveness of the audit. Audit & Supervisory Board members attend the Board of Directors meetings and other important meetings and monitor the business execution of directors according to audit policies and audit plans.

Also, as a general rule, a meeting of the Group's Audit & Supervisory Board members is convened quarterly to share information, strengthen coordination, and 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.

## 4. 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.

## 5. Director Remuneration and Other

Remuneration structure of the Company's directors is designed to correspond to the director's responsibilities, taking into account motivational influence for the sustainable growth of the Company, the increase of corporate value over the medium- to long-term, and recruitment of superior personnel. The Company strives to make the remuneration structure objective, utilizing external data and other measures.

Director remuneration consists of fixed monthly remuneration, annual bonuses linked to performance, and medium- to long-term performance-based share remuneration-type stock options. Outside directors receive only fixed monthly remuneration.

### (1) Policies for Setting Director Remuneration Amounts and Determining Calculation Methods and Method for Deciding

The director remuneration structure is designed so that talented human resources can be hired and retained and to provide strong motivation to excel in job performance, thus contributing to sustainable improvements in the Company's earnings and value.

#### a. Amount of Director Remuneration at the Company as a holding company

Director remuneration at the Company as a holding company consists of fixed remuneration set depending on position, bonuses linked to performance to provide short-term incentives and stock options to provide medium- to long-term incentives.

At the Annual Shareholders' Meeting held on June 29, 2010, it was resolved that fixed remuneration and performance-based bonuses would be capped at ¥1,500 million.

The fixed remuneration is determined in light of the duties and responsibilities (duties and responsibilities involving devising and deciding on Group strategy, monitoring Group management and strengthening corporate governance) of the director of the holding company.

The performance-based bonus is determined based on (1) consolidated net income in that fiscal year and the degree to which annual performance targets have been met; (2) progress in achieving medium- to long-term consolidated earnings targets and (3) implementation of management based on appropriate corporate governance, as well as the individual's own performance.

The remuneration-type stock options are determined so that performance of duties over the medium- to long-term are reflected in enhanced corporate earnings and value in the future.

#### b. Amount of Director Remuneration at Subsidiaries as Operating Companies

Remuneration for directors at subsidiaries, which are operating companies, is determined based on the duties and responsibilities (executing the business of each operating company based on the Group strategies devised by the Company as well as duties and responsibilities involving devising and deciding on the strategy of each operating company, and strengthening corporate governance) of the directors of the operating company, and is not to exceed the cap on director remuneration resolved at the Shareholders' Meeting.

#### c. Amount of Remuneration for Company's Audit & Supervisory Board members

Audit & Supervisory Board members are only paid base remuneration, which does not fluctuate based on performance. At the Annual Shareholders' Meeting held on June 29, 2010, it was resolved that base remuneration would be capped at ¥80 million. The exact amount, not to exceed the cap, is decided in discussion by the Audit & Supervisory Board members.

### (2) Total Remuneration by Officer Category, Total Remuneration by Type and Number of Applicable Officers

Officer category	Total remuneration and other (¥ million)	Total remuneration by type (¥ million)			Number of applicable officers (people)
		Base remuneration	Amount charged as cost of stock options	Bonus	
<b>Directors</b> (excluding outside directors)	370	251	—	119	6
<b>Audit &amp; Supervisory Board members</b> (excluding outside Audit & Supervisory Board members)	33	33	—	—	2
<b>Outside directors</b>	45	45	—	—	5

## Change in fiscal year end

Following approval of the partial amendments of the Articles of Incorporation at the 6th Annual Shareholders' Meeting held on June 27, 2014, the Company changed its consolidated fiscal year end from March 31 to December 31.

As a result, the consolidated statements of income and consolidated statements of comprehensive income are consolidated based on the period from April 1 to December 31 for FY2014 and from January 1 to December 31 for FY2015.

## Financial highlights (Graphs 1, 3 and 4)

During the fiscal year ended December 31, 2015, the global economy showed signs of a slowdown with the noteworthy exception of the U.S. Major factors were lower growth rates across emerging markets, particularly China, and falling commodity prices.

While economic policy in Japan once again focused on reviving core economic growth, the rise in social insurance costs remains to be a central theme in Japan's fiscal restructuring. Consequently, policies aimed at curbing healthcare spending continued to put further pressure on pharmaceutical industry revenues. However, since Japan's "Healthy Life Expectancy" policy is fully aligned with our longstanding corporate philosophy to contribute to "people's health," we expect that new business opportunities that contribute to public health will ultimately result in strategic opportunities for the Otsuka Group (the "Group").

During 2015, the Group recorded consolidated net sales of ¥1,445,227 million for the current fiscal year, with operating income of ¥151,837 million and net income of ¥84,086 million.

## Operating results by business segment (Graphs 2, 3, 4 and 5)

### 1) Pharmaceuticals

Net sales of the pharmaceutical segment were ¥971,843 million consisting mainly of global sales of *ABILIFY*, clinical nutrition, *Samsca*, and *Abilify Maintena*.

### 2) Nutraceuticals

Net sales of the nutraceutical segment were ¥330,203 million consisting mainly of sales of *Pocari Sweat*, *Oronamin C*, *Calorie Mate* 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 ¥43,200 million consisting mainly of sales of *MATCH*, *CRYSTAL GEYSER*, and *Bon Curry*.

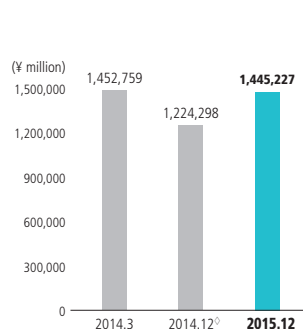
### 4) Others

Net sales of the other segment were ¥145,193 million 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 totaled ¥844,119 million resulting in an operating income of ¥151,837 million. Major components of selling, general and administrative expenses included personnel expenses (¥152,513 million), sales promotion expenses (¥195,560 million) and research and development expenses (¥201,010 million).

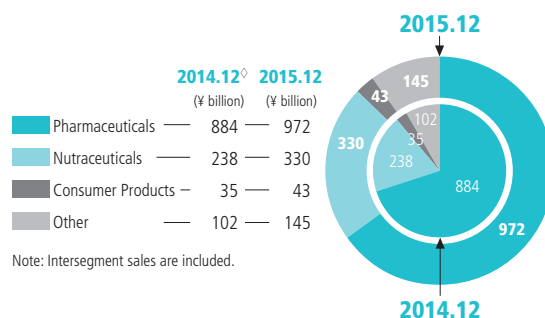
Graph 1

### Net Sales



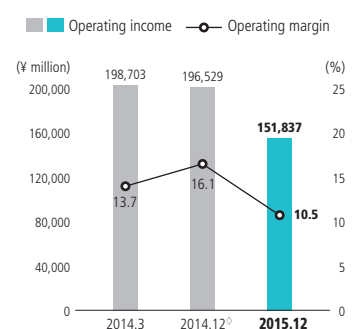
Graph 2

### Sales by Business Segment



Graph 3

### Operating Income



◇ 2014.12 (FY2014) represents nine months.

Other expenses, totaling ¥13,670 million, included equity in earnings of unconsolidated subsidiaries and affiliated companies (¥8,032 million) and impairment loss (¥18,820 million).

As a result, net income was ¥84,086 million.

## Financial position (Graph 6)

Total assets as of December 31, 2015 were ¥2,528,510 million, an increase of ¥350,326 million compared to ¥2,178,184 million at the end of the previous fiscal year, December 31, 2014. The increase was due to a ¥68,721 million decrease in current assets and a ¥419,047 million increase in non-current assets.

### Assets

#### (Current Assets)

Total current assets as of December 31, 2015 were ¥1,176,882 million, a decrease of ¥68,721 million compared to ¥1,245,603 million at the end of the previous fiscal year. This was mainly due to decreases of ¥27,845 million in short-term investments, ¥23,661 million in trade accounts, and ¥21,015 million in receivables for unconsolidated subsidiaries and affiliated companies.

#### (Non-current Assets)

Total non-current assets as of December 31, 2015 were ¥1,351,628 million, an increase of ¥419,047 million compared to ¥932,581 million at the end of the previous fiscal year. This increase was mainly due to an ¥11,638 million increase in property, plant and equipment including new investments at Otsuka Warehouse's West Japan Logistics Center, and increases of ¥205,195 million in in-process research and development, ¥140,810 million in goodwill, and

¥75,315 million in intangible assets due to the full consolidation of Avanir Pharmaceuticals, Inc.

### Liabilities

#### (Current Liabilities)

Total current liabilities as of December 31, 2015 were ¥467,076 million, an increase of ¥30,049 million compared to ¥437,027 million at the end of the previous fiscal year. This was mainly due to an increase of ¥108,076 million in accrued expenses, despite decreases of ¥47,351 million in trade accounts and ¥20,404 million in short-term borrowing.

#### (Long-term Liabilities)

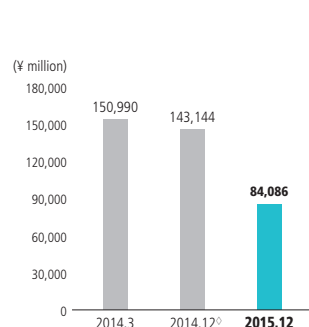
Total long-term liabilities as of December 31, 2015 were ¥377,998 million, an increase of ¥295,441 million compared to ¥82,557 million at the end of the previous fiscal year. This increase mainly resulted from increases of ¥211,456 million in long-term debt related to the acquisition of Avanir Pharmaceuticals, Inc. and ¥87,915 million in deferred tax liabilities.

### Equity

Total equity as of December 31, 2015 was ¥1,683,436 million, an increase of ¥24,836 million compared to ¥1,658,600 million at the end of the previous fiscal year. This was mainly due to payment of ¥48,764 million in dividends, a ¥34,866 million increase in total shareholders' equity as a result of net income of ¥84,086 million, and a ¥7,921 million decrease in accumulated other comprehensive income (decrease in net assets) influenced by stock market and exchange rate movements.

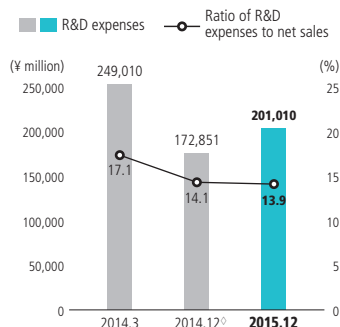
Graph 4

### Net Income



Graph 5

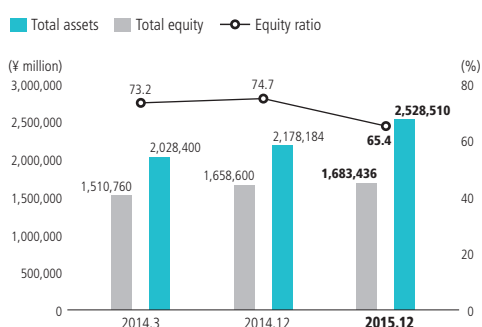
### R&D Expenses



◇ 2014.12 (FY2014) represents nine months.

Graph 6

### Total Assets, Total Equity and Equity Ratio



## Cash flows (Graph 7)

Cash and cash equivalents increased by ¥4,069 million during the fiscal year ended December 31, 2015 to ¥460,609 million. Net cash provided by operating activities and financing activities was ¥253,873 million and ¥176,505 million, respectively, while net cash used in investing activities was ¥420,056 million.

### (Cash Flows from Operating Activities)

Net cash provided by operating activities was ¥253,873 million in the fiscal year ended December 31, 2015. Contributing factors were ¥138,167 million in income before income taxes and minority interest, a ¥97,555 million increase in accrued expenses, ¥71,477 million in depreciation and amortization, and a ¥47,495 million decrease in trade payables.

### (Cash Flows from Investing Activities)

Net cash used in investing activities was ¥420,056 million in the fiscal year ended December 31, 2015. Main investing activities included ¥392,527 million in investments in subsidiaries resulting in a change in scope of consolidation, ¥57,256 million in purchases of property, plant and equipment, and a decrease of ¥29,603 million in short-term investments.

### (Cash Flows from Financing Activities)

Net cash provided by financing activities was ¥176,505 million in the fiscal year ended December 31, 2015. Main financing activities included ¥266,694 million in proceeds from long-term debt, ¥24,407 million in repayments of long-term debt, ¥48,764 million in dividends paid, and a ¥16,102 million decrease in short-term borrowings.

## Operational risks

The Group's business performance is subject to various risks, and may experience unexpected fluctuations due to the occurrence of risk events, despite the Group's effort to take preventive measures to avoid potential risks. Below are assumed risk factors that could cause a major impact on the Group's performance and financial position. However, there can be no assurance that these listed items represent all risks, and there may be other potential risks that could affect the Group's performance and business activities. Forward-looking statements contained in these items are envisioned based on the information available as of December 31, 2015.

### (1) Risk as a holding company

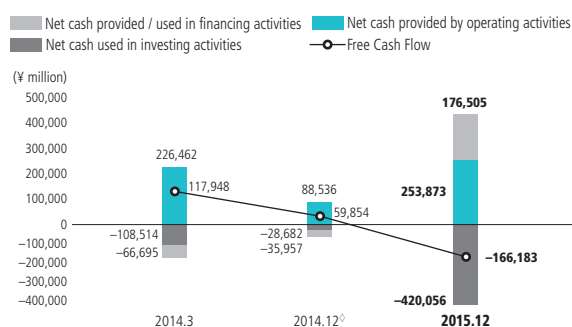
The Company was established on July 8, 2008 as a pure holding company to strengthen the Group's overall corporate governance structure by directing the Group's strategic planning, allocating operating resources, and monitoring Group operations. The Company receives dividends and appropriate management fees from its subsidiaries in order to secure stable income. However, the Company's performance and financial position may be materially impacted depending on the subsidiaries' earnings conditions.

### (2) Risk related to side effects

In the pharmaceutical business, clinical trials necessary for the approval of new drugs are conducted with limited numbers of participants, and thus there can be no assurance that the approved new drugs are safe for all the recipients, and side effects that were unknown at the time of launch may emerge. The Group takes out an appropriate liability insurance including product liability, but this may not fully cover the damages that the Group may be liable for. As a result, there may be significant impact on the Group's performance and financial position should any side effects emerge in the pharmaceutical products that the Group manufactures or sells and the Group may be obliged to recall or discontinue the sales. This could also adversely affect the Group's social trust, brand, and business operations.

Graph 7

## Cash Flows



◇ 2014.12 (FY2014) represents nine months.



### (3) Risk related to R&D

Although development programs for pharmaceutical products require significant investment and time, the development may be postponed or discontinued depending on the clinical trial results. The Group is also subject to applicable laws and regulations in Japan and other jurisdictions that regulate pharmaceutical products, including approval processes that involve significant uncertainties in terms of the length of time required for approval and whether the products meet the criteria of the respective regulatory authorities with respect to efficacy and safety requirements. These factors could result in unexpected delays in, or the termination of, initial plans to launch new products. There can be no assurance that any investment made in researching and developing products will be recouped if the launch of pharmaceutical products is terminated or postponed. Although the Group works to prevent the above risks by focusing on unmet medical needs and enhancing multiple pipelines, not all risks are evitable and this uncertainty in development may cause significant impact on the Group's performance and financial results.

### (4) Risk related to reliance on a specific product

Net sales of the Group's top-selling pharmaceutical product *ABILIFY* constitute approximately 20% of the Group's total consolidated net sales.

It is possible that sales of *ABILIFY* may decrease due to other competing products, expiration of the patent protection term\*, and sales of generic pharmaceutical products as a result of unfavorable verdicts on patent effectiveness, or for any other reason, which could materially and adversely affect the Group's performance and financial position.

\* Substance patents related to *ABILIFY* are scheduled to expire in Japan in January 2016 (including a two-year extension of the re-examination period due to the conducting of pediatric clinical trials). The patent has already expired in the U.S. in April 2015 (including the additional six-month pediatric exclusive period) and in Europe in October 2014.

### (5) Risk related to government policies to reduce medical costs

In Japan, the Ministry of Health, Labour and Welfare has been reducing National Health Insurance prices for drugs and promoting use of generic drugs in order to curtail growing medical expenses.

Similarly in the U.S., a significant Group market, there has been increasing pricing pressure on brand drugs from managed care institutions, insurance companies and the Patient Protection and Affordable Care Act enacted in March 2010 as well as promotion of low-price generic drugs. Further implementation of such policies may have a material impact on the Group's performance and financial condition.

### (6) Risk related to consumer trends

The Group sells products (especially beverage products) in its nutraceutical business and consumer products business that are subject to fluctuations in demand based on consumer sentiment influenced by the weather and the economic environment. A change in consumer buying trends could cause a material impact on the Group's performance and financial condition.

### (7) Risk related to food safety

The Group takes every possible measure to secure food safety for the customer not only in in-house products but also products by contract manufacturers. In recent years, however, both the domestic and international food industry have faced various problems such as contamination with harmful substances. The Group's performance, financial condition, and social trust may be significantly impacted should there be any incidents that exceed the Group's quality control capacity.

### (8) Risk related to rising raw material price

The raw material price is subjected to fluctuation due to various factors including weather, natural disaster, market price, economic situation, fuel expense, and currency exchange. The manufacturing cost could rise if raw material prices rise for some reason. The Group intends to shift the cost increases to sales price, but there may be significant impact on the Group's performance and financial results should there be difficulties with the market situation, negotiation with clients, or procurement of raw materials due to problems with suppliers.

#### **(9) Risk related to laws and regulations**

The Group's subsidiaries and affiliated companies which operate in the pharmaceutical business are subject to rigid regulations under the Pharmaceutical Affairs Law, and obtain approvals and licenses to operate their various business activities. In order to receive these approvals and licenses, the Group works hard to comply with terms, conditions, and related regulations. At present there are no grounds for the revocation of these approvals and licenses. However, in the event of approvals and licenses being revoked due to violation of laws, the Group may be required to recall and terminate certain products, or discontinue certain business, which could result in a significant impact on the Group's operations and business activities.

#### **(10) Risk related to expiration of patent protection**

Although the Group works to extend the life cycle of pharmaceutical products by adding indications or changing the formulation of medicine, the pharmaceutical products that the Group manufactures and sells could be exposed to severe competition with generics once the patent protection term during which the Group can exercise market exclusivity terminates. As a result, there may be significant impact on the Group's performance and financial condition.

#### **(11) Risk related to patent infringement**

While the Group strictly manages intellectual property rights including patents, and always keeps careful watch for potential infringement by a third party, expected earnings may be lost if the intellectual property rights held by the Group or licensed to the Group by other companies are infringed by a third party.

Also, while the Group always keeps careful watch for potential infringement of the intellectual property rights of a third party by the Group, the Group may be required to recall, terminate manufacturing and sales, and pay substantial amounts of compensation if a Group in-house product is proven to have infringed a third party's intellectual property rights.

#### **(12) Risk related to litigation**

Regarding the Group's operational activities, there is a possibility that a suit may be brought to court relating to product liability, labor issues, patent infringement, breach of contract, environmental pollution, etc. As a result, there may be a significant impact on the Group's performance, financial condition, operational strategies and social trust should there be a judgment, decision or settlement unfavorable to the Group.

#### **(13) Risk related to shutdown of manufacturing base**

The Group's manufacturing facilities are dispersed in various regions in order to hedge against unexpected disaster, war, terrorism, broad-scale system failure, accidents, etc. However, in the case all or part of these manufacturing facilities were to shut down, or all or part of product manufacturing were to become impossible or significantly difficult temporarily or in the long term, this might impact the Group's performance and financial results significantly.

#### **(14) Risk related to environmental pollution**

The Group is subject to various environmental protection laws and regulations regarding waste generated in the process of manufacturing and atmospheric emission in the various regions in which the Group operates. The Group works to manage environmental burdens and reduce environmental risks by assessing the impact on the environment that each business operation has. As a result, the Group has not experienced any material environmental violations in the past, but there can be no assurance that there will not be any environmental violation in the future. In the case soil or air contamination were to be found, legal actions might be required by the authorities and related expenditures and liability for damages could arise, which as a result could negatively affect the Group's performance, financial results, social trust and brands.

**(15) Risk related to foreign exchange and stock price**

In the fiscal year ended December 31, 2015, 55.8% of the Group's net sales were from customers outside of Japan, and a significant portion of net sales will continue to be based on foreign currencies from sources outside of Japan. There is a possibility that the Group's performance may be significantly impacted by a sharp appreciation of the yen in foreign exchange that exceeds the Company's expectation. In addition, because the financial statements of the Group's foreign subsidiaries and affiliated companies are denominated in foreign currencies, the foreign exchange may have significant impact on the Group's performance and financial results when converting to yen.

If the stock market becomes weak, the Group's performance and financial results may be significantly impacted by the valuation loss of the stocks that the Group holds and the increase of net defined benefit liability due to the decrease of the pension plan assets.

**(16) Risk related to business alliances and acquisitions**

From time to time, the Group enters into technology alliances, business alliances, establishment of joint venture companies, partnership with third parties and acquisition of third-party businesses in connection with research and development, manufacturing and sales activities. Regarding these alliances, the Group thoroughly assesses the business synergy, the business performance and the credibility of the partner. Regarding capital alliance and acquisition, the Group is committed to detailed due diligence regarding the financial position and contract relationships of the third party to lower the risk. However, if the business environment changes after entering into the alliance or for other reasons, the alliances may not have the effect that the Group originally anticipated or the alliance may be terminated for any other reason, which as a result could have a significant impact on the Group's performance and financial position. When the alliance is to be contracted, the Group may experience material restriction of its future business strategies if it is obliged not to compete in certain regions, periods, or products.

**(17) Risk related to the operation of businesses in foreign countries**

Outside of Japan, the Group conducts business operations mainly in the U.S., Europe and Asia, including research and development, manufacturing and sales activities. The Group is thus subject to risks related to maintaining global operations, including foreign laws and regulations, the economic environment, political instability and uncertainty in the business environment, and as a result there may be severe impact on the Group's performance and financial results.

**(18) Risk related to information management**

The Group holds various material information including personal information. Regarding the management of this information, the Group is committed to maintain rules and regulations, educate employees in the importance of information management and create secure systems. However, there still is a possibility that there may be risks where information falsification, fraudulence, and leakage could occur due to system malfunctions and accidents. As a result, the Group's performance and social trust might be adversely affected.

# Consolidated Balance Sheet

Otsuka Holdings and its Consolidated Subsidiaries as of December 31, 2015

ASSETS	Notes	Millions of Yen		Thousands of U.S. Dollars (Note 1)
		2015.12	2014.12	2015.12
<b>Current assets:</b>				
Cash and cash equivalents	7,16	¥ 460,609	¥ 456,540	\$ 3,818,995
Short-term investments	3,16	42,354	70,199	351,165
Marketable securities	4,16	64,016	44,932	530,769
Receivables:	7,15,16			
Trade notes		7,441	10,806	61,695
Trade accounts		369,543	393,204	3,063,950
Unconsolidated subsidiaries and affiliated companies		4,267	25,282	35,378
Other		11,539	7,552	95,672
Allowance for doubtful receivables		(733)	(541)	(6,077)
Inventories	5	144,889	153,711	1,201,302
Deferred tax assets	11	32,455	37,783	269,090
Other current assets	15	40,502	46,135	335,809
Total current assets		1,176,882	1,245,603	9,757,748
<b>Property, plant and equipment:</b>				
Land	6,7	82,287	82,784	682,257
Buildings and structures		365,989	352,971	3,034,483
Machinery and equipment		381,873	373,883	3,166,180
Furniture and fixtures		92,353	88,869	765,716
Lease assets		13,586	14,600	112,644
Construction in progress		20,791	17,890	172,382
Total property, plant and equipment		956,879	930,997	7,933,662
Accumulated depreciation		(600,457)	(586,213)	(4,978,501)
Net property, plant and equipment		356,422	344,784	2,955,161
<b>Investments and other assets:</b>				
Investment securities	4,16	113,606	112,847	941,929
Investments in and advances to unconsolidated subsidiaries and affiliated companies	15,16	193,728	206,014	1,606,235
Goodwill	6	233,972	93,162	1,939,905
Intangible assets	6	170,220	94,905	1,411,326
In-process research and development	6	238,301	33,106	1,975,798
Deferred tax assets	11	7,398	15,476	61,338
Net defined benefit asset	8	22,770	17,486	188,790
Other assets		15,211	14,801	126,118
Total investments and other assets		995,206	587,797	8,251,439
Total		¥2,528,510	¥2,178,184	\$20,964,348

The accompanying notes are an integral part of these statements.

## LIABILITIES AND EQUITY

		Millions of Yen		Thousands of U.S. Dollars (Note 1)
	Notes	2015.12	2014.12	2015.12
<b>Current liabilities:</b>				
Short-term borrowings	7, 16	¥ 44,442	¥ 64,846	\$ 368,477
Current portion of long-term debt	7, 16	37,363	7,552	309,784
Payables:	15, 16			
Trade notes		7,406	8,487	61,405
Trade accounts		73,857	121,208	612,362
Construction		5,513	23,833	45,709
Unconsolidated subsidiaries and affiliated companies		2,399	3,101	19,891
Other		59,924	76,123	496,841
Income taxes payable	16	19,336	14,498	160,318
Accrued expenses		184,381	76,305	1,528,737
Other current liabilities		32,455	41,074	269,090
<b>Total current liabilities</b>		<b>467,076</b>	<b>437,027</b>	<b>3,872,614</b>
<b>Long-term liabilities:</b>				
Long-term debt	7, 16	239,528	28,072	1,985,971
Net defined benefit liability	8	9,753	10,922	80,864
Retirement benefits for directors, audit and supervisory board members		2,496	2,788	20,695
Negative goodwill		17,227	19,691	142,832
Long-term unearned revenues		137	147	1,136
Deferred tax liabilities	11	99,942	12,027	828,638
Other long-term liabilities		8,915	8,910	73,916
<b>Total long-term liabilities</b>		<b>377,998</b>	<b>82,557</b>	<b>3,134,052</b>
<b>Commitments and contingent liabilities</b>				
<b>Equity:</b>				
Common stock:	9, 10, 22	81,691	81,691	677,315
Authorized — 1,600,000,000 shares as of December 31, 2015 and 2014				
Issued — 557,835,617 shares as of December 31, 2015 and 2014				
Capital surplus		512,702	512,747	4,250,908
Stock acquisition rights		—	—	—
Retained earnings		1,025,663	990,906	8,503,963
Treasury stock, at cost:		(47,262)	(47,416)	(391,858)
15,985,891 shares as of December 31, 2015				
16,037,940 shares as of December 31, 2014				
Accumulated other comprehensive income:				
Unrealized gain on available-for-sale securities		27,053	13,152	224,301
Deferred gain on derivatives under hedge accounting		130	393	1,078
Foreign currency translation adjustments		41,749	57,161	346,150
Defined retirement benefit plans	8	13,020	19,167	107,951
<b>Total</b>		<b>1,654,746</b>	<b>1,627,801</b>	<b>13,719,808</b>
Minority interests		28,690	30,799	237,874
<b>Total equity</b>		<b>1,683,436</b>	<b>1,658,600</b>	<b>13,957,682</b>
<b>Total</b>		<b>¥2,528,510</b>	<b>¥2,178,184</b>	<b>\$20,964,348</b>

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Income

Otsuka Holdings and its Consolidated Subsidiaries as of December 31, 2015

	Notes	Millions of Yen		Thousands of U.S. Dollars (Note 1)
		2015.12	2014.12	2015.12
<b>Net sales</b>	12	<b>¥1,445,227</b>	¥1,224,298	<b>\$11,982,647</b>
<b>Cost of sales</b>		<b>449,271</b>	346,300	<b>3,724,990</b>
Gross profit		<b>995,956</b>	877,998	<b>8,257,657</b>
<b>Selling, general and administrative expenses</b>	13	<b>844,119</b>	681,469	<b>6,998,748</b>
Operating income		<b>151,837</b>	196,529	<b>1,258,909</b>
<b>Other income (expenses):</b>				
Interest and dividend income		<b>3,263</b>	2,237	<b>27,054</b>
Interest expense		<b>(4,105)</b>	(1,658)	<b>(34,035)</b>
Foreign exchange gain (loss), net		<b>(2,999)</b>	12,872	<b>(24,865)</b>
Amortization of negative goodwill		<b>2,695</b>	1,848	<b>22,345</b>
Equity in earnings of unconsolidated subsidiaries and affiliated companies		<b>8,032</b>	3,874	<b>66,595</b>
Loss on impairment of long-lived assets	6	<b>(18,820)</b>	(5,378)	<b>(156,040)</b>
Loss on valuation of investment securities, investments in unconsolidated subsidiaries and affiliated companies	4	<b>(3,400)</b>	(1,483)	<b>(28,190)</b>
Gain on change in equity interest		<b>518</b>	124	<b>4,294</b>
Other, net		<b>1,146</b>	1,301	<b>9,501</b>
Other income (expenses), net		<b>(13,670)</b>	13,737	<b>(113,341)</b>
<b>Income before income taxes and minority interests</b>		<b>138,167</b>	210,266	<b>1,145,568</b>
<b>Income taxes:</b>	11			
Current		<b>37,754</b>	46,219	<b>313,025</b>
Deferred		<b>18,692</b>	19,833	<b>154,979</b>
Total income taxes		<b>56,446</b>	66,052	<b>468,004</b>
<b>Net income before minority interests</b>		<b>81,721</b>	144,214	<b>677,564</b>
<b>Minority interests in net income</b>		<b>(2,365)</b>	1,070	<b>(19,609)</b>
<b>Net income</b>		<b>¥ 84,086</b>	¥ 143,144	<b>\$ 697,173</b>

	Notes	Yen		U.S. Dollar (Note 1)
		2015.12	2014.12	2015.12
<b>Per share of common stock:</b>	2(t), 21			
Basic net income		<b>¥155.13</b>	¥264.20	<b>\$1.29</b>
Diluted net income		<b>155.11</b>	264.12	<b>1.29</b>
Cash dividends applicable to the year		<b>100.00</b>	75.00	<b>0.83</b>

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Comprehensive Income

Otsuka Holdings and its Consolidated Subsidiaries as of December 31, 2015

	Notes	Millions of Yen		Thousands of U.S. Dollars (Note 1)
		2015.12	2014.12	2015.12
<b>Net income before minority interests</b>		<b>¥81,721</b>	¥144,214	<b>\$677,564</b>
<b>Other comprehensive income (loss):</b>	19			
Unrealized gain (loss) on available-for-sale securities		<b>14,000</b>	(761)	<b>116,077</b>
Deferred gain (loss) on derivatives under hedge accounting		<b>(263)</b>	398	<b>(2,181)</b>
Foreign currency translation adjustments		<b>(9,322)</b>	42,402	<b>(77,290)</b>
Defined retirement benefit plans		<b>(6,235)</b>	(976)	<b>(51,696)</b>
Share of other comprehensive income in affiliated companies		<b>(7,582)</b>	12,327	<b>(62,864)</b>
Total other comprehensive income		<b>(9,402)</b>	53,390	<b>(77,954)</b>
<b>Comprehensive income</b>	19	<b>¥72,319</b>	¥197,604	<b>\$599,610</b>
<b>Total comprehensive income attributable to:</b>	19			
Owners of the parent		<b>¥75,896</b>	¥194,330	<b>\$629,268</b>
Minority interests		<b>(3,577)</b>	3,274	<b>(29,658)</b>

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Changes in Equity

Otsuka Holdings and its Consolidated Subsidiaries as of December 31, 2015

	Thousands Outstanding number of shares of common stock	Notes	Millions of Yen											
			Common stock	Capital surplus	Stock acquisition rights	Retained earnings	Treasury stock	Accumulated other comprehensive income				Total	Minority interests	Total equity
								Unrealized gain on available-for- sale securities	Deferred gain (loss) on derivatives under hedge accounting	Foreign currency translation adjustments	Defined retirement benefit plans			
<b>Balance as of April 1, 2014</b>	541,624		¥ 81,691	¥ 512,896	¥ 105	¥ 886,315	¥ (47,929)	¥ 13,820	¥ (7)	¥ 12,153	¥ 20,331	¥ 1,479,375	¥ 26,085	¥ 1,505,460
Cash dividends, ¥70 per share						(37,915)						(37,915)		(37,915)
Net income						143,144						143,144		143,144
Disposal of treasury stock	174			(149)			514					365		365
Purchase of treasury stock							(1)					(1)		(1)
Change in scope of consolidation		2(a)				(816)						(816)		(816)
Increase in retained earnings due to change of fiscal year end						178						178		178
Net change in the year					(105)			(668)	400	45,008	(1,164)	43,471	4,714	48,185
<b>Balance as of December 31, 2014</b>	541,798		¥ 81,691	¥ 512,747	¥ —	¥ 990,906	¥ (47,416)	¥ 13,152	¥ 393	¥ 57,161	¥ 19,167	¥ 1,627,801	¥ 30,799	¥ 1,658,600
Cash dividends, ¥90 per share						(48,764)						(48,764)		(48,764)
Net income						84,086						84,086		84,086
Disposal of treasury stock	53			(45)			155					110		110
Purchase of treasury stock	(1)						(1)					(1)		(1)
Change in scope of consolidation		2(a)(d)				(565)						(565)		(565)
Net change in the year								13,901	(263)	(15,412)	(6,147)	(7,921)	(2,109)	(10,030)
<b>Balance as of December 31, 2015</b>	541,850		¥ 81,691	¥ 512,702	¥ —	¥ 1,025,663	¥ (47,262)	¥ 27,053	¥ 130	¥ 41,749	¥ 13,020	¥ 1,654,746	¥ 28,690	¥ 1,683,436

The accompanying notes are an integral part of these statements.

	Notes	Thousands of U.S. Dollars (Note 1)											
		Common stock	Capital surplus	Stock acquisition rights	Retained earnings	Treasury stock	Accumulated other comprehensive income				Total	Minority interests	Total equity
							Unrealized gain on available-for- sale securities	Deferred gain (loss) on derivatives under hedge accounting	Foreign currency translation adjustments	Defined retirement benefit plans			
<b>Balance as of December 31, 2014</b>		\$ 677,315	\$ 4,251,281	\$ —	\$ 8,215,786	\$ (393,135)	\$ 109,046	\$ 3,258	\$ 473,933	\$ 158,917	\$ 13,496,401	\$ 255,360	\$ 13,751,762
Cash dividends, \$0.75 per share					(404,311)						(404,311)		(404,311)
Net income					697,173						697,173		697,173
Disposal of treasury stock			(373)			1,285					912		912
Purchase of treasury stock						(8)					(8)		(8)
Change in scope of consolidation		2(a)(d)			(4,685)						(4,685)		(4,685)
Net change in the year							115,255	(2,180)	(127,783)	(50,966)	(65,674)	(17,486)	(83,161)
<b>Balance as of December 31, 2015</b>		\$ 677,315	\$ 4,250,908	\$ —	\$ 8,503,963	\$ (391,858)	\$ 224,301	\$ 1,078	\$ 346,150	\$ 107,951	\$ 13,719,808	\$ 237,874	\$ 13,957,682

The accompanying notes are an integral part of these statements.

# Consolidated Statement of Cash Flows

Otsuka Holdings and its Consolidated Subsidiaries as of December 31, 2015

	Notes	Millions of Yen		Thousands of U.S. Dollars (Note 1)
		2015.12	2014.12	2015.12
<b>Operating activities:</b>				
Income before income taxes and minority interests		¥138,167	¥210,266	\$1,145,568
Adjustments for:				
Income taxes paid		(18,165)	(88,481)	(150,609)
Depreciation and amortization		71,477	45,538	592,629
Amortization of negative goodwill		(2,695)	(1,848)	(22,345)
Equity in earnings of unconsolidated subsidiaries and affiliated companies		(8,032)	(3,874)	(66,595)
Loss on impairment of long-lived assets		18,820	5,378	156,040
Loss on valuation of investment securities, investments in unconsolidated subsidiaries and affiliated companies		3,400	1,483	28,190
Changes in assets and liabilities:				
Decrease (increase) in trade receivables		27,444	(61,285)	227,543
Decrease in inventories		14,818	17,700	122,859
Decrease in trade payables		(47,495)	(3,886)	(393,790)
Decrease in long-term unearned revenues		(11)	(5,567)	(91)
Decrease in liability for retirement benefits		(9,841)	(9,584)	(81,594)
Decrease in payables - other		(16,420)	(9,881)	(136,141)
Increase in accrued expenses		97,555	2,536	808,846
Other, net		(15,149)	(9,959)	(125,603)
Net cash provided by operating activities		253,873	88,536	2,104,907
<b>Investing activities:</b>				
(Increase) decrease in marketable securities		(7,604)	19,594	(63,046)
Proceeds from sales of property, plant and equipment		1,631	499	13,523
Purchases of property, plant and equipment		(57,256)	(32,888)	(474,720)
Purchases of intangible assets		(15,583)	(7,072)	(129,202)
Proceeds from sales and redemptions of investment securities		10,060	1,347	83,409
Purchases of investment securities		(3,998)	(4,985)	(33,148)
Purchases of stock of unconsolidated subsidiaries and affiliated companies		(1,748)	(4,807)	(14,493)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	20	(392,527)	(26,704)	(3,254,515)
Decrease in short-term investments		29,603	28,500	245,444
Payments of loans receivable from unconsolidated subsidiaries and affiliated companies		(895)	(2,753)	(7,421)
Other, net		18,261	587	151,406
Net cash used in investing activities		(420,056)	(28,682)	(3,482,763)
<b>Financing activities:</b>				
Decrease in short-term borrowings		(16,102)	(4,202)	(133,505)
Proceeds from long-term debt		266,694	9,393	2,211,210
Repayments of long-term debt		(24,407)	(1,820)	(202,363)
Purchase of treasury stock		(7)	(1)	(58)
Proceeds from disposal of treasury stock		110	366	912
Dividends paid		(48,764)	(37,915)	(404,311)
Dividends paid to minority interests in consolidated subsidiaries		(416)	(363)	(3,449)
Proceeds from share issuance to minority shareholders		866	808	7,180
Other, net		(1,469)	(2,223)	(12,180)
Net cash provided by (used in) financing activities		176,505	(35,957)	1,463,436
<b>Foreign currency translation adjustments on cash and cash equivalents</b>				
		(8,796)	14,282	(72,928)
<b>Net increase in cash and cash equivalents</b>				
		1,526	38,179	12,652
<b>Cash and cash equivalents of newly consolidated subsidiaries</b>				
		2,543	951	21,084
<b>Cash and cash equivalents, beginning of year</b>				
		456,540	417,410	3,785,259
<b>Cash and cash equivalents, end of year</b>				
		¥460,609	¥456,540	\$3,818,995

The accompanying notes are an integral part of these statements.



## 1. Basis of presenting consolidated financial statements

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in 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 consolidated financial statements of the fiscal year ended December 31, 2014 to conform to the classifications used in the fiscal year ended December 31, 2015. The accompanying consolidated financial statements, significant accounting policies, and other information have not been audited by an independent auditor.

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 ¥120.61 to US\$1, the approximate rate of exchange as of December 31, 2015. 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) Basis for preparing consolidated financial statements

The consolidated financial statements as of December 31, 2015 include the accounts of the Company and its 112 (102 as of December 31, 2014) significant subsidiaries. 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 December 31, 2014) unconsolidated subsidiary and 15 (16 as of December 31, 2014) affiliated companies are accounted for by the equity method.

During the fiscal year ended December 31, 2015, Avanir Pharmaceuticals, Inc., Biocentury, S.L.U., and four other companies were newly included in the scope of consolidation from the fiscal year ended December 31, 2015 as a result of the acquisition of their shares.

Otsuka Wellness Vending Co., Ltd., Taiho Oncology, Inc., Otsuka Chemical America, Inc., and four other companies were newly included in the scope of consolidation from the fiscal year ended December 31, 2015 due to their increase in materiality.

Diatranz Otsuka Limited which had been an affiliated company accounted for by the equity method was included in the scope of consolidation from the fiscal year ended December 31, 2015 as it has become a subsidiary.

Bigarade Corporation, a previously consolidated subsidiary, was absorbed by Avanir Pharmaceuticals, Inc., a consolidated subsidiary of the Group. Also, Nardobel Participacoes Ltda., a previously consolidated subsidiary, was absorbed by Jasmine Comercio de Produtos Alimenticios LTDA, a consolidated subsidiary of the Group.

Otsuka America Foods, Inc. a previously consolidated subsidiary, was excluded from the scope of consolidation upon liquidation. Also, American Peptide Company, Inc., a previously consolidated subsidiary, was excluded from the scope of consolidation as a result of sale of its all shares.

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

The excess of cost of investments in consolidated subsidiaries over fair value of their net assets or the excess of net assets of consolidated subsidiaries over purchase cost at the date of acquisition is amortized on a straight-line basis over a period of five 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 may be used tentatively 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 affiliated 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 affiliates' accounting policies for similar transactions and events under similar circumstances to those of the parent company when the affiliates' financial statements are used in applying the equity method, unless it is impracticable to determine adjustments. In addition, financial statements prepared by foreign affiliated companies in accordance with either International Financial Reporting Standards or U.S. GAAP may be used tentatively 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 combinations**

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 periodically 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 revised standard was applicable to business combinations undertaken on or after April 1, 2010.

Business combinations due to acquisition

- (1) Overview of Business Combination
  - 1) Name of company acquired and nature of business  
Name of company acquired: Avanir Pharmaceuticals, Inc.  
Nature of business: Research, development, manufacturing and marketing of pharmaceutical products
  - 2) Rationale for business combination  
Avanir Pharmaceuticals, Inc. ("Avanir") is a biopharmaceutical venture company specializing in the area of central nervous system ("CNS") diseases. It was founded in 1988 in Southern California and now employs approximately 500 people. Avanir developed and launched *NUDEXTA*<sup>®</sup> (dextromethorphan hydrobromide/quinidine

sulfate) 20 mg/10 mg capsules in the U.S. in February 2011 as the world's first and only approved treatment for the PBA. Avanir markets *NUDEXTA* in the U.S. through its own sales organization of over 300 sales representatives, 150 of whom are medical representatives hired to accelerate the continued growth of *NUDEXTA* for PBA.

The company's pipeline includes programs in Alzheimer-type dementia, Parkinson's disease, migraine, and other CNS indications. The promising new chemical entity AVP-786, with a target indication for behavioral disorders (agitation) associated with Alzheimer-type dementia, is being prepared to enter Phase III clinical trials.

The acquisition of Avanir will bring Otsuka Pharmaceutical Co., Ltd. ("Otsuka Pharmaceutical") three distinct values: 1. *NUDEXTA*, created to treat the under-recognized neurologic disease PBA; 2. the late-stage investigational compound AVP-786 in clinical development to treat agitation associated with Alzheimer-type dementia; and 3. Avanir's clinical development and commercial expertise in neurologic diseases, which complements Otsuka Pharmaceutical's capabilities in psychiatric diseases. These will accelerate Otsuka Pharmaceutical's existing expansion strategy in the neurologic area, widening the overall CNS portfolio, inclusive of the psychiatric and neurologic areas, supporting both short- and medium-term growth.

This acquisition is consistent with the Otsuka Group's investment philosophy: invest in companies and businesses with which we can share a common management philosophy, human resources, products and technology to enhance corporate value, and invest with a long-term perspective. The acquisition is based on Otsuka's central concepts of creativity and proof through execution.

- 3) Date of business combination  
January 13, 2015 (U.S. Eastern Standard Time)
- 4) Legal type of business combination  
All-cash tender offer
- 5) Name of resulting entity  
Avanir Pharmaceuticals, Inc.
- 6) Share of voting rights acquired  
100%
- 7) Main rationale for selecting the acquiring entity  
The acquisition company (Bigarade Corporation), a subsidiary of the Company, has acquired all shares of Avanir Pharmaceuticals, Inc. for cash.

- (2) Period of Performance of the Acquired Company Included in the Consolidated Financial Statements  
January 13, 2015 to December 31, 2015
- (3) Total Acquisition Price and Breakdown  
Acquisition price: US\$3,507 million in cash  
Direct costs related to the acquisition: US\$20 million
- (4) Amount and Reason for Recognition of Goodwill Arising from the Acquisition, Amortization Method and Period of Goodwill
  - 1) Amount of goodwill recognized  
¥160,633 million
  - 2) Reason for recognition of goodwill  
Since the acquisition price exceeded the net amount of acquired assets and liabilities, the exceeding amount was recognized as goodwill.
  - 3) Amortization method and period of goodwill  
Straight-line method over 20 years
- (5) The Amount and Major Breakdown of Assets Acquired and Liabilities Assumed on the Date of the Business Combination

	(Millions of yen)
Current assets	¥ 41,309
Non-current assets	299,710
<b>Total assets</b>	<b>341,019</b>
Current liabilities	11,013
Long-term liabilities	76,813
<b>Total liabilities</b>	<b>¥ 87,826</b>

- (6) Amount Allocated to Intangible Assets other than Goodwill, its Breakdown by Major Types, and Weighted Average Amortization Period by Major Types
  - 1) Amount allocated to intangible assets  
¥298,671 million
  - 2) Breakdown by major types  
Distribution rights and others: ¥96,449 million  
In-process research and development: ¥202,221 million
  - 3) Weighted average amortization period by major types  
Distribution rights and others: 12 years  
In-process research and development: Planned to be amortized over the expected period of use.
- (7) Estimated Amount and Calculation Method of the Impact on the Consolidated Statement of Income for the Current Fiscal Year Assuming that the Business Combination had been Completed at the Beginning of the Current Fiscal Year Omitted due to immateriality.

#### (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 and booked in 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 is calculated mainly by the straight-line method over the estimated useful lives of the assets.

The range of useful lives is from two to 65 years for buildings and structures and from two to 58 years for machinery and equipment.

**(i) Intangible assets**

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

**(j) Impairment loss**

The Group reviews its long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or an asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or an 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 the 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 consist of contributory funded corporate pension plans and lump-sum retirement payments plans.

Certain foreign consolidated subsidiaries have contributory funded or unfunded defined benefit pension plans, defined contributory pension plans, or a combination of them.

In order to cover payments of retirement benefits to employees, the net amount after deducting plan assets from retirement benefit obligations is recognized as net defined benefit liability (net defined benefit asset, in the event plan assets exceed retirement benefit obligations) based on the estimated amount as of the current fiscal year end.

(1) Methods of attributing estimated retirement benefits to accounting periods

When calculating retirement benefit obligations, the benefit formula is used to attribute estimated benefits to the period through the end of the current fiscal year.

(2) Recognition of actuarial gains and losses, prior service costs, and transitional obligations

Actuarial gains and losses are amortized in the succeeding years by the straight-line method over a certain number of years equal to or less than the average remaining service period of employees (5–20 years) at the time of occurrence.

Prior service costs are amortized by the straight-line method over a certain number of years equal to or less than the average remaining service period of employees (5–23 years) at the time of occurrence.

Transitional obligations are amortized over 5 to 15 years.

**(l) 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 property, plant and equipment and is associated with the retirement of such property, plant and equipment. 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 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 when 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.

#### **(p) Income taxes**

The provision for income taxes is calculated 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 tax assets and liabilities are calculated 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 except when they are hedged by forward exchange contracts.

#### **(r) Foreign currency translation**

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

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

#### **(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 calculated 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 fiscal 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 fiscal years, including dividends to be paid after the end of the fiscal 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 found, those statements are restated.

#### **[Changes in Presentation]**

##### **(Consolidated Balance Sheets)**

In the previous fiscal year, "In-process research and development" was included in "Intangible assets," however, it is now separately presented due to its increased materiality in the amount. To reflect this change in method of presentation, the consolidated financial statements for the previous fiscal year have been reclassified accordingly.

As a result, ¥128,011 million previously presented as "Intangible assets" is now presented as ¥33,106 million in "In-process research and development" and ¥94,905 million in "Intangible assets."

##### **(Consolidated Statements of Income)**

In the previous fiscal year, "Gain on change in equity interest" was included in "Other, net" under "Other income (expenses)," however, it is now separately presented due to its increased materiality in the amount. To reflect this change in the method of presentation, the consolidated financial statements for the previous fiscal year have been reclassified accordingly.

As a result, ¥1,425 million previously presented as "Other, net" under "Other income (expenses)" is now presented as ¥124 million in "Gain on change in equity interest" and ¥1,301 million in "Other, net."

##### **(Consolidated Statements of Cash Flows)**

In the previous fiscal year, "Decrease in payables - other" and "Increase in accrued expenses" were included in "Other, net" under "Operating activities," however, these items are now separately presented due to their increased materiality. To reflect this change in the method of presentation, the consolidated financial statements for the previous fiscal year have been reclassified accordingly.

As a result, ¥(17,304) million previously presented as "Other, net" under "Operating activities" is now presented as ¥(9,881) million in "Decrease in payables - other," ¥2,536 million in "Increase in accrued expenses," and ¥(9,959) million in "Other, net."

**(v) Accounting Standards to be adopted**

(Accounting Standards for Business Combination)

On September 13, 2013, the ASBJ issued following revised statements and guidance:

- "Accounting Standard for Business Combinations" (ASBJ Statement No. 21)
- "Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22)
- "Accounting Standard for Business Divestitures" (ASBJ Statement No. 7)
- "Accounting Standard for Net Income Per Share" (ASBJ Statement No.2)
- "Guidance on Accounting Standards for Business Combinations and Business Divestitures" (ASBJ Guidance No. 10)
- "Guidance on Accounting Standard for Net Income Per Share" (ASBJ Guidance No.4)

**(1) Overview**

- Under the revised accounting standard, any difference between the fair value of the consideration received or paid and the amount by which the minority interest is adjusted shall be accounted for as capital surplus as long as the parent retains control over its subsidiary. In the consolidated balance sheet, "minority interest" under the current accounting standard will be changed to "noncontrolling interest" under the revised accounting standard.
- Under the revised accounting standard, acquisition-related costs shall be accounted for as expenses in the periods in which the costs are incurred.
- 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.
- 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.

**(2) Scheduled effective date**

Beginning of fiscal year ending December 2016

**(3) Effect of applying the revised standards**

The effect of applying the revised standards on consolidated financial statements is not determined.

(Implementation Guidance on Recoverability of Deferred Tax Assets)

On December 28, 2015, the ASBJ issued following revised guidance:

- "Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No. 26)

**(1) Overview**

Under the revised guidance, revisions are required for the following points;

- 1) Treatment of companies which do not fall under in any of (category 1) to (category 5)
- 2) Requirements on categorizing (category 2) and (category 3)
- 3) Treatment of deductible temporary differences that is impossible to schedule for companies in (category 2)
- 4) Treatment of reasonable period of estimating taxable income before adjustments for temporary differences for companies in (category 3)
- 5) Treatment of companies in (category 4) when they also meet (category 2) or (category 3)

**(2) Scheduled effective date**

Beginning of fiscal year ending December 2017

**(3) Effect of applying the revised standards**

The effect of applying the revised standards on consolidated financial statements is under evaluation.

### 3. Short-term investments

Short-term investments as of December 31, 2015 and 2014 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Time deposits	¥42,354	¥70,199	\$351,165
Total	¥42,354	¥70,199	\$351,165

### 4. Securities

Securities as of December 31, 2015 and 2014 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
<b>Current:</b>			
Government and corporate bonds	¥ 19,484	¥ 43,932	\$161,545
Certificate of deposit	44,532	1,000	369,224
Total current	¥ 64,016	¥ 44,932	\$530,769
<b>Non-current:</b>			
Marketable equity securities	¥ 81,040	¥ 61,737	\$671,918
Government and corporate bonds	13,674	35,138	113,374
Certificate of deposit	1,245	—	10,322
Other	17,647	15,972	146,315
Total non-current	¥113,606	¥112,847	\$941,929

The costs and aggregate fair values of marketable and investment securities as of December 31, 2015 and 2014 were as follows:

December 31, 2015	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Securities classified as:</b>				
<b>Available for sale:</b>				
Equity securities	¥42,952	¥38,782	¥694	¥81,040
Held to maturity	78,935	199	130	79,004

December 31, 2014	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Securities classified as:</b>				
<b>Available for sale:</b>				
Equity securities	¥43,030	¥20,270	¥1,563	¥61,737
Held to maturity	80,070	220	3	80,287

December 31, 2015	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Securities classified as:</b>				
<b>Available for sale:</b>				
Equity securities	\$356,123	\$321,549	\$5,754	\$671,918
Held to maturity	654,465	1,650	1,078	655,037

Available-for-sale securities whose fair values were not determinable are disclosed in Note 16.(4)(b).

The information of available-for-sale securities, which were sold during the fiscal years ended December 31, 2015 and 2014 was as follows:

December 31, 2015	Millions of Yen		
	Proceeds	Realized Gains	Realized Losses
<b>Available for sale:</b>			
Equity securities	¥4,357	¥2,821	¥8
Total	¥4,357	¥2,821	¥8

December 31, 2014	Millions of Yen		
	Proceeds	Realized Gains	Realized Losses
<b>Available for sale:</b>			
Equity securities	¥345	¥—	¥5
Total	¥345	¥—	¥5

December 31, 2015	Thousands of U.S. Dollars		
	Proceeds	Realized Gains	Realized Losses
<b>Available for sale:</b>			
Equity securities	\$36,125	\$23,389	\$66
Total	\$36,125	\$23,389	\$66

The impairment losses on equity securities for the fiscal years ended December 31, 2015 and 2014 were ¥3,400 million (US\$28,190 thousand) and ¥1,483 million, respectively.

### 5. Inventories

Inventories as of December 31, 2015 and 2014 consisted the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Finished products and merchandise	¥ 71,255	¥ 80,011	\$ 590,789
Work in process	34,726	31,784	287,920
Raw materials and supplies	38,908	41,916	322,593
Total	¥144,889	¥153,711	\$1,201,302

### 6. Long-lived assets

The Group reviewed its long-lived assets for impairment as of December 31, 2015. As a result, the Group recognized an impairment loss of ¥18,820 million (US\$156,040 thousand) for business properties due to decline in profitability of each business segment and for certain business properties related to each business segment due to low capacity utilization.



Impairment losses, which the Group recognized for the fiscal years ended December 31, 2015 and 2014 were as follows:

Pharmaceuticals:	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Goodwill and in-process research and development	¥ 6,760	¥ —	\$ 54,048
Intangible assets	7,582	—	62,864
Buildings and structures	243	1,179	2,015
Machinery and equipment	51	3,601	423
Other	145	116	1,202
Total	¥14,781	¥4,896	\$122,552

Nutraceuticals:	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Intangible assets	¥ 61	¥ —	\$ 506
Buildings and structures	—	59	—
Machinery and equipment	232	111	1,923
Other	—	6	—
Total	¥293	¥176	\$2,429

Consumer products:	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Buildings and structures	¥—	¥10	\$—
Machinery and equipment	—	44	—
Other	—	25	—
Total	¥—	¥79	\$—

Other:	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Land	¥ 4	¥ 1	\$ 33
Goodwill and in-process research and development	3,620	—	30,014
Total	¥3,624	¥1	\$30,047

Corporate:	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Land	¥122	¥226	\$1,012
Total	¥122	¥226	\$1,012

The Group bases its grouping for assessing impairment losses on its business segments. However, certain assets such as idle assets are evaluated on an individual basis. The recoverable amounts in each business segment were measured mainly at their value in use. Discount rate of 6.4% and 11.0% were mainly used for the computation of present value of future cash flows for certain business properties in each business segment. The use of a discount rate was omitted due to the negative cash flows for other assets. The recoverable amount of the impaired idle assets was measured at net realizable value as determined based mainly on real estate appraisals.

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

Short-term borrowings as of December 31, 2015 and 2014 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Unsecured loans from banks and financial institutions			
With a weighted-average interest rate of 1.9% (2015.12) and with a weighted-average interest rate of 1.2% (2014.12)	¥44,442	¥64,846	\$368,477
Total	¥44,442	¥64,846	\$368,477

Long-term debt as of December 31, 2015 and 2014 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Secured loans from banks and financial institutions			
Due 2016 to 2024, with a weighted-average interest rate of 3.3% (2015.12) and due 2015 to 2022, with a weighted-average interest rate of 4.1% (2014.12)	¥ 1,973	¥ 2,158	\$ 16,359
Unsecured loans from banks and financial institutions			
Due 2016 to 2023, with a weighted-average interest rate of 0.9% (2015.12) and due 2015 to 2021, with a weighted-average interest rate of 1.2% (2014.12)	267,494	25,426	2,217,843
Unsecured straight bonds by a consolidated subsidiary			
Due 2016, with a weighted-average interest rate of 0.8% (2015.12) and due 2015 to 2016, with a weighted-average interest rate of 0.8% (2014.12)	20	100	166
Unsecured lease liabilities	7,404	7,940	61,387
Total	276,891	35,624	2,295,755
Less-portion due within one year			
Loans	37,302	5,332	309,278
Straight bonds	20	80	166
Lease liabilities	41	2,140	340
Long-term debt, less current portion	¥239,528	¥28,072	\$1,985,971

Annual maturities of long-term debt as of December 31, 2015 were as follows:

Fiscal years ending December 31	Millions of Yen	Thousands of U.S. Dollars
2016	¥ 37,363	\$ 309,784
2017	42,071	348,819
2018	41,565	344,623
2019	40,289	334,044
2020	37,799	313,399
2021 and thereafter	77,804	645,086
Total	¥276,891	\$2,295,755

The carrying amounts of assets pledged as collateral for long-term debt as of December 31, 2015 were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Cash and cash equivalents	¥ 65	\$ 539
Property, plant and equipment - net of accumulated depreciation	3,131	25,960
Total	¥3,196	\$26,499

## 8. 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 unfunded defined benefit pension plans or defined contributory pension plans, or a combination of them.

### Defined benefit pension plan

(1) The changes in defined benefit obligation for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Balance at beginning of fiscal year	¥225,437	¥198,159	\$1,869,140	
Cumulative effect of changes in accounting policies	—	8,319	—	
Balance after cumulative effect	225,437	206,478	1,869,140	
Current service cost	8,289	5,504	68,726	
Interest cost	3,223	2,955	26,722	
Actuarial (gains) losses	(603)	14,696	(5,000)	
Benefits paid	(10,189)	(7,498)	(84,479)	
Change in scope of consolidation	2	154	17	
Foreign currency translation adjustment	(491)	2,966	(4,071)	
Others	(28)	182	(232)	
Balance at end of fiscal year	¥225,640	¥225,437	\$1,870,823	

(2) The changes in plan assets for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Balance at beginning of fiscal year	¥232,001	¥201,142	\$1,923,564	
Expected return on plan assets	6,401	4,330	53,072	
Actuarial (losses) gains	(4,215)	18,777	(34,947)	
Contributions from the employer	14,386	13,034	119,277	
Benefits paid	(9,926)	(7,275)	(82,298)	
Foreign currency translation adjustment	(69)	2,058	(573)	
Others	79	(65)	654	
Balance at end of fiscal year	¥238,657	¥232,001	\$1,978,749	

(3) Reconciliation between the liability (asset) recorded in the consolidated balance sheet and the balances of defined benefit obligation and plan assets as of December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Funded defined benefit obligation	¥222,588	¥222,260	\$1,845,519	
Plan assets	(238,657)	(232,001)	(1,978,749)	
	(16,069)	(9,741)	(133,230)	
Unfunded defined benefit obligation	3,052	3,177	25,304	
Net asset arising from defined benefit obligation	(13,017)	(6,564)	(107,926)	
Net defined benefit liability	9,753	10,922	80,864	
Net defined benefit asset	(22,770)	(17,486)	(188,790)	
Net asset arising from defined benefit obligation	¥(13,017)	¥(6,564)	\$ (107,926)	

(4) The components of net periodic benefit costs for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Service cost	¥ 8,289	¥5,504	\$68,726	
Interest cost	3,223	2,955	26,722	
Expected return on plan assets	(6,401)	(4,330)	(53,072)	
Amortization of prior service cost	(4,176)	(2,905)	(34,624)	
Recognized actuarial gains	(2,224)	(2,270)	(18,440)	
Amortization of transitional obligation	13	11	108	
Extra retirement payments	249	244	2,065	
Net periodic benefit costs	¥(1,027)	¥(791)	\$ (8,515)	

(5) Other comprehensive income before adjusting tax effects on defined retirement benefit plans for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Actuarial (losses) gains	¥(7,780)	¥ 739	\$(64,505)	
Prior service cost	(2,229)	(2,272)	(18,481)	
Transitional obligation	13	11	107	
Total	¥(9,996)	¥(1,522)	\$(82,879)	

(6) Accumulated other comprehensive income before adjusting tax effects on defined retirement benefit plans for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	2015.12	2014.12	2015.12	
Unrecognized actuarial gains	¥11,759	¥19,583	\$ 97,496	
Unrecognized prior service cost	7,273	9,488	60,302	
Unrecognized transitional obligation	(21)	(33)	(174)	
Total	¥19,011	¥29,038	\$157,624	

## (7) Plan assets

## a. Components of plan assets

Plan assets consisted of the following:

	2015.12	2014.12
Debt investments	43%	42%
Equity investments	25%	32%
Others	32%	26%
Total	100%	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.

## (8) Assumptions used for the fiscal years ended December 31, 2015 and 2014 were set forth as follows:

	2015.12	2014.12
Discount rate	0.90 - 9.00%	0.98 - 9.25%
Expected rate of return on plan assets	1.00 - 9.00%	2.50 - 8.00%

## (9) Contributions to defined contribution pension plan for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Contributions to defined contribution pension plan	¥5,772	¥3,105	\$47,857

## 9. 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.

## 10. Stock options

The stock option activity for the fiscal year ended December 31, 2015 is as follows:

December 31, 2015	2010 Stock Option No. 2	2010 Stock Option No. 4
<b>Nonvested:</b>		
December 31, 2014 – Outstanding	—	—
Granted	—	—
Canceled	—	—
Vested	—	—
December 31, 2015 – Outstanding	—	—
<b>Vested:</b>		
December 31, 2014 – Outstanding	15,000 shares	177,920 shares
Vested	—	—
Exercised	7,000 shares	45,555 shares
Canceled	8,000 shares	132,365 shares
December 31, 2015 – Outstanding	—	—
Exercise price	¥2,100 (\$17)	¥2,100 (\$17)
Average stock price at exercise	¥4,015 (\$33)	¥3,761 (\$31)
Fair value price at grant date	—	—

## 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:

- 1) The total intrinsic value of the stock options for the years ended December 31, 2014 was ¥293 million.
- 2) The total intrinsic value of the stock option rights on the exercise date for the fiscal year ended December 31, 2015 and 2014 was ¥88 million (US\$730 thousand) and ¥286 million, respectively.

## 11. 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 35.6% for both fiscal years ended December 31, 2015 and 2014.

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, as of December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
<b>Deferred tax assets:</b>			
Liability for retirement benefits	¥ 3,260	¥ 3,786	\$ 27,029
Unrealized intercompany profits from inventories	5,202	18,362	43,131
Accrued expenses	19,603	8,997	162,532
Accrued enterprise tax	1,519	1,250	12,594
Tax loss carryforwards	52,870	28,556	438,355
Research and development expenses	42,412	44,896	351,646
Loss on devaluation of investment securities	5,177	4,557	42,923
Loss on impairment of long-lived assets	4,954	5,314	41,075
Long-term unearned revenue	788	4,395	6,533
Other	15,444	11,015	128,049
Less valuation allowance	(39,816)	(33,629)	(330,122)
<b>Total deferred tax assets</b>	<b>111,413</b>	<b>97,499</b>	<b>923,745</b>
<b>Deferred tax liabilities:</b>			
Unrealized gain on available-for-sale securities	12,621	7,096	104,643
Asset for retirement benefits	7,560	6,240	62,681
Unrealized gain on full revaluation resulting from inclusion of consolidated subsidiaries	135,443	27,265	1,122,983
Revaluation of brands	3,976	3,963	32,966
Other	11,902	11,703	98,682
<b>Total deferred tax liabilities</b>	<b>171,502</b>	<b>56,267</b>	<b>1,421,955</b>
<b>Net deferred tax assets</b>	<b>¥(60,089)</b>	<b>¥41,232</b>	<b>\$ (498,210)</b>

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 fiscal years ended December 31, 2015 and 2014 were as follows:

	2015.12	2014.12
Normal effective statutory tax rate	35.6%	35.6%
Tax credit for research and development expenses	(7.2)	(8.6)
Reduction of ending deferred tax balance due to change in statutory tax rate	1.9	—
Expenses not deductible for income tax purposes	1.3	0.6
Valuation allowance	3.9	0.3
Difference in statutory tax rate of subsidiaries	(1.5)	(0.4)
Equity in earnings of affiliated companies	(1.2)	(0.3)
Branded Prescription Drug Fee	1.8	2.5
Other – net	6.3	1.7
<b>Actual effective tax rate</b>	<b>40.9%</b>	<b>31.4%</b>

Tax rates including corporate tax changed from the consolidated fiscal year starting on and after April 1, 2015, according to "partial amendment of the income tax act" (regulations in 2015, No.9) and "partial amendment of the local tax act" (regulation in 2015, No. 2) which were published on March 31, 2015.

Therefore, as for temporary differences presumed to resolve after the consolidated fiscal year starting on and after January 1, 2016, the effective tax rate used for the calculation of deferred tax assets and liabilities changes from 35.6% to 33.0%. In addition, as for temporary differences presumed to resolve after the consolidated fiscal year starting on and after January 1, 2017, the effective tax rate used for the calculation of deferred tax assets and liabilities changes from 35.6% to 32.2%.

These changes decreased the net deferred tax assets (after deduction of deferred tax liability) by ¥628 million (US\$ 5,207 thousand), increased adjustments for corporate taxes by ¥2,559 million (US\$ 21,220 thousand), adjustments for valuations of other securities by ¥1,228 million (US\$ 10,188 thousand), accumulated adjustments for retirement benefits by ¥697 million (US\$ 5,786 thousand), deferred hedge profit or loss by ¥4 million (US\$ 39 thousand), respectively.

As of December 31, 2015, certain consolidated subsidiaries had tax loss carryforwards aggregating ¥52,870 million (US\$438,356 thousand) which are available to be offset against taxable income of such subsidiaries in future fiscal years. These tax loss carryforwards, if not utilized, will expire as follows:

Fiscal years ending December 31	Millions of Yen	Thousands of U.S. Dollars
2016	¥ 693	\$ 5,746
2017	1,959	16,242
2018	2,358	19,551
2019	1,331	11,036
2020 and thereafter	46,529	385,781
<b>Total</b>	<b>¥52,870</b>	<b>\$438,356</b>

## 12. Up-front licensing payments received

Net sales recognized as revenue from the up-front licensing payments received for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Up-front licensing payments received	¥66,050	¥20,368	\$547,633

## 13. Selling, general and administrative expenses

Selling, general and administrative expenses for the fiscal years ended December 31, 2015 and 2014 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Sales promotion expenses	¥195,560	¥188,010	\$1,621,424
Personnel expenses	152,513	97,860	1,264,514
Depreciation	31,768	22,897	263,394
Amortization of goodwill	13,991	3,813	116,002
Research and development expenses	201,010	172,851	1,666,611
Other	249,277	196,038	2,066,803
Selling, general and administrative expenses	¥844,119	¥681,469	\$6,998,748

## 14. Leases

The Group leases certain assets, mainly machinery and equipment.

The future minimum lease payments under noncancelable operating leases as of December 31, 2015 were as follows:

2015.12	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 4,430	\$ 36,730
Due after one year	14,025	116,284
Total	¥18,455	\$153,014

## 15. Related-party transactions

(1) The material related-party transactions for the fiscal year ended December 31, 2015 were as follows:

(a) Related-party transactions between the Company and related parties (limited to individuals)

Type	Name	Relationship	Ownership (Owned) percentage	Transaction detail	Transaction amount	
					Millions of Yen	Thousands of U.S. Dollars
Audit & Supervisory Board Member	Hiroshi Sugawara	Outside Audit & Supervisory Board Member of the Company	(Owned) Direct 0.0%	Exercise of stock option (Note 1)	¥12	\$99
Close family member of Director	Yujiro Otsuka	Advisor	(Owned) Direct 0.0%	Payment of consulting fee (Note 2)	24	199

(b) Related-party transactions between the Group and related parties (limited to individuals)

Type	Name	Contrmts of Bussiness or Relationship	Ownership (Owned) percentage	Transaction detail	Transaction amount (Note 3)		Account	Transaction amount (Note 3)	
					Millions of Yen	Thousands of U.S. Dollars		Millions of Yen	Thousands of U.S. Dollars
Company whose majority of shares is owned by Director and his/her close family member	Tokushima Yakuin Co., Ltd. (Note 4)	Pharmaceutical wholesaler	—	Purchase of raw materials by Otsuka Pharmaceutical Co., Ltd. and others	¥813	\$6,741	Payables: Trade accounts	¥46	\$381
							Payables: Other	2	17
Close family member of Director	Yujiro Otsuka	Advisor	(Owned) Direct 0.0%	Payment of consulting fee from Otsuka Warehouse Co., Ltd and others (Note 2)	33	274	—	—	
Close family member of Director of significant subsidiary	Yukio Kobayashi	Special advisor of Taiho Pharmaceutical Co., Ltd.	(Owned) Direct 0.2%	Payment of consulting fee from Taiho Pharmaceutical Co., Ltd. (Note 2)	24	199	—	—	

(2) The material related-party transactions for the fiscal year ended December 31, 2014 were as follows:

(a) Related-party transactions between the Company and related parties (limited to individuals)

Type	Name	Relationship	Ownership (Owned) percentage	Transaction detail	Transaction amount
					Millions of Yen
Director	Ichiro Otsuka	Vice chairman and Representative Director of the Company	(Owned) Direct 0.2% Indirect 0.9% (Note 5)	Condolence Payment (Note 6)	¥60
Close family member of Director	Kyoichi Komatsu	Chairman and Representative Director of Otsuka Pharmaceutical Factory, Inc.	(Owned) Direct 0.0%	Exercise of stock option (Note 1)	15

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

Type	Name	Business Description	Ownership (Owned) percentage	Transaction detail	Transaction amount (Note 3)	Account	Transaction amount (Note 3)	
					Millions of Yen		Millions of Yen	
Affiliated Company	MicroPort Scientific Corporation	Medical Business (Holding Company)	(Owned) Indirect 33.2%	Loans (Note 7, 8, 9)	¥ —	Receivables: Unconsolidated subsidiaries and affiliated companies (Short-term loan receivable)	¥19,288	
							Investments in and advances to unconsolidated subsidiaries and affiliated companies (long-term loan receivable)	4,822
							Interest Income (Note 7)	231
						Other current assets (Accrued interest)	156	

(c) Related-party transactions between the Group and related parties (limited to individuals)

Type	Name	Conrmts of Business or Relationship	Ownership (Owned) percentage	Transaction detail	Transaction amount (Note 3)	Account	Transaction amount (Note 3)
					Millions of Yen		Millions of Yen
Company whose majority of shares is owned by Director and his/her close family member	Tokushima Yakuhin Co., Ltd. (Note 4)	Pharmaceutical wholesaler	—	Purchase of raw materials by Otsuka Pharmaceutical Co., Ltd. and others	¥659	Payables: Trade accounts	¥ 79
							Payables: Other
Director	Ichiro Otsuka	Vice Chariman and Representative Director of the Company	(Owned) Direct 0.2% Indirect 0.9% (Note 5)	Condolence payment from: Otsuka Pharmaceutical Co., Ltd. and others (Note 6)	122	Payables: Other	112
Close family member or Director	Yujiro Otsuka	Advisor	(Owned) Direct 0.0%	Payment of consulting fee from Otsuka Warehouse Co., Ltd and others (Note 2)	25	—	—
Close family member of Director of significant subsidiary	Yukio Kobayashi	Special advisor of Taiho Pharmaceutical Co., Ltd.	(Owned) Direct 0.2%	Payment of consulting fee from Taiho Pharmaceutical Co., Ltd. (Note 2)	18	—	—

Notes:

1. 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. Payment is decided by agreement between the two parties based on the details of the consulting agreement.
3. Excluding consumption tax.
4. Close family member of the Director of the Company owns a majority of the shares of Tokushima Yakuhin Co., Ltd.
5. Shares in the Otsuka Founders Shareholding Fund Trust Account are included for the calculation of the indirectly owned percentage.
6. This refers to condolence money paid to the surviving family of Akihiko Otsuka, Chairman and Representative Director of the Company. The amount paid was calculated in accordance with the payment standard stipulated in the rules of the Company based on a resolution of the Board of Directors.
7. Interest rate is mutually agreed upon based on market rates.
8. Otsuka Medical Devices Co., Ltd. accepts business-related assets, including inventories and securities from subsidiaries of MicroPort Scientific Corporation as collateral for loans. Transaction amount of collateral equals to the balance of receivables as of December 31, 2014.
9. Part of loans includes the conversion rights to the MicroPort Scientific Corporation stock.

## 16. Financial instruments and related disclosures

### (1) Group policy for financial instruments

The Group limits its investments to low-risk financial assets and uses borrowings from financial institutions, mainly banks, for its financing needs. Derivatives are used, not for speculative purposes, but to manage exposure to financial risks as described in (2) below.

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

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

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

Derivatives mainly include forward foreign currency contracts, which are used to manage exposure to market risks from changes in foreign currency exchange rates of receivables and payables, and interest rate swaps, which are used to manage exposure to changes in interest rates of bank loans. Please see Note 17. 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 17. 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 17. 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 17. for the details of fair value for derivatives.

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

December 31, 2015	Millions of Yen		
	Carrying amount	Fair value	Unrealized gain
Cash and cash equivalents	¥ 460,609	¥ 460,609	¥ —
Short-term investments	42,354	42,354	—
Receivables	392,057	392,057	—
Marketable and investment securities	159,975	160,045	70
Investments in and advances to unconsolidated subsidiaries and affiliated companies	45,577	122,841	77,264
<b>Total</b>	<b>¥1,100,572</b>	<b>¥1,177,906</b>	<b>¥77,334</b>
Short-term borrowings	¥44,442	¥ 44,442	¥ —
Payables	149,099	149,099	—
Income tax payable	19,336	19,336	—
Long-term debt (excluding straight bonds issued by a consolidated subsidiary and lease liabilities)	269,467	269,233	(234)
<b>Total</b>	<b>¥ 482,344</b>	<b>¥ 482,110</b>	<b>¥ (234)</b>

December 31, 2014	Millions of Yen		
	Carrying amount	Fair value	Unrealized gain
Cash and cash equivalents	¥ 456,540	¥ 456,540	¥ —
Short-term investments	70,199	70,199	—
Receivables	436,303	436,303	—
Marketable and investment securities	141,807	142,024	217
Investments in and advances to unconsolidated subsidiaries and affiliated companies	49,305	103,457	54,152
<b>Total</b>	<b>¥1,154,154</b>	<b>¥1,208,523</b>	<b>¥54,369</b>
Short-term borrowings	¥64,846	¥64,846	¥ —
Payables	232,752	232,752	—
Income tax payable	14,498	14,498	—
Long-term debt (excluding straight bonds issued by a consolidated subsidiary and lease liabilities)	27,584	27,538	(46)
<b>Total</b>	<b>¥ 339,680</b>	<b>¥ 339,634</b>	<b>¥ (46)</b>

December 31, 2015	Thousands of U.S. Dollars		
	Carrying amount	Fair value	Unrealized gain
Cash and cash equivalents	\$3,818,995	\$3,818,995	\$ —
Short-term investments	351,165	351,165	—
Receivables	3,250,618	3,250,618	—
Marketable and investment securities	1,326,383	1,326,963	580
Investments in and advances to unconsolidated subsidiaries and affiliated companies	377,887	1,018,497	640,610
<b>Total</b>	<b>\$9,125,048</b>	<b>\$9,766,238</b>	<b>\$641,190</b>
Short-term borrowings	\$368,477	\$ 368,477	\$ —
Payables	1,236,208	1,236,208	—
Income tax payable	160,318	160,318	—
Long-term debt (excluding straight bonds issued by a consolidated subsidiary and lease liabilities)	2,234,202	2,232,261	(1,941)
<b>Total</b>	<b>\$3,999,205</b>	<b>\$3,997,264</b>	<b>\$ (1,941)</b>

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

The carrying values are used as fair values for cash and cash equivalents, short-term investments, and receivables 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 4.

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

The carrying values are used as fair values for payables, short-term borrowings, and income tax payable 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 17.

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

	Millions of Yen		Thousands of U.S. Dollars
	Carrying amount		
	2015.12	2014.12	2015.12
Investments in and advances to unconsolidated subsidiaries and affiliated companies	¥148,151	¥156,709	\$1,228,347
Investment securities	17,647	15,972	146,315

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

December 31, 2015	Millions of Yen			
	Due in one year or less	Due after one year through five years	Due after five years through 10 years	Due after 10 years
Cash and cash equivalents	¥460,609	¥ —	¥ —	¥ —
Short-term investments	42,354	—	—	—
Receivables	391,795	255	7	—
Marketable and investment securities:				
Held-to-maturity securities	18,016	17,929	—	—
Available-for-sales securities	43,000	—	—	—
<b>Total</b>	<b>¥955,774</b>	<b>¥18,184</b>	<b>¥ 7</b>	<b>¥ —</b>

December 31, 2015	Thousands of U.S. Dollars			
	Due in one year or less	Due after one year through five years	Due after five years through 10 years	Due after 10 years
Cash and cash equivalents	\$3,818,995	\$ —	\$ —	\$ —
Short-term investments	351,165	—	—	—
Receivables	3,248,446	2,114	58	—
Marketable and investment securities:				
Held-to-maturity securities	149,374	148,653	—	—
Available-for-sales securities	356,521	—	—	—
<b>Total</b>	<b>\$7,924,501</b>	<b>\$150,767</b>	<b>\$58</b>	<b>\$ —</b>

Please see Note 7. for annual maturities of long-term debt, obligations under finance leases and straight bonds.



## 17. 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.

Derivative 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 as of December 31, 2015 and 2014 were as follows:

Millions of Yen				
December 31, 2015	Contract amount	Contract amount due after one year	Fair value	Unrealized loss
Foreign currency forward contracts:				
Buying U.S. \$	¥1,011	¥—	¥(14)	¥(14)
Buying Euro	1,033	—	11	11
Buying JP ¥	76	—	(1)	(1)
Buying Canadian \$	803	—	(65)	(65)
<b>Total</b>	<b>¥2,923</b>	<b>¥—</b>	<b>¥(69)</b>	<b>¥(69)</b>

Millions of Yen				
December 31, 2014	Contract amount	Contract amount due after one year	Fair value	Unrealized loss
Foreign currency forward contracts:				
Buying U.S. \$	¥721	¥—	¥(1)	¥(1)
Buying Euro	1,003	—	5	5
Buying JP ¥	121	—	(3)	(3)
Buying Canadian \$	133	—	(3)	(3)
<b>Total</b>	<b>¥1,978</b>	<b>¥—</b>	<b>¥(2)</b>	<b>¥(2)</b>

Thousands of U.S. Dollars				
December 31, 2015	Contract amount	Contract amount due after one year	Fair value	Unrealized loss
Foreign currency forward contracts:				
Buying U.S. \$	\$ 8,382	\$—	\$(116)	\$(116)
Buying Euro	8,565	—	91	91
Buying JP ¥	630	—	(8)	(8)
Buying Canadian \$	6,658	—	(539)	(539)
<b>Total</b>	<b>\$24,235</b>	<b>\$—</b>	<b>\$(572)</b>	<b>\$(572)</b>

Derivative transactions to which hedge accounting is applied as of December 31, 2015 and 2014 were as follows:

Millions of Yen				
December 31, 2015	Hedged item	Contract amount	Contract amount due after one year	Fair value
Foreign currency forward contracts:				
Buying U.S. \$	Forecasted transactions	¥ 430	¥—	¥ 6
Selling U.S. \$	Forecasted transactions	8,610	—	188
<b>Total</b>		<b>¥9,040</b>	<b>¥—</b>	<b>¥194</b>

Millions of Yen				
December 31, 2014	Hedged item	Contract amount	Contract amount due after one year	Fair value
Foreign currency forward contracts:				
Buying U.S. \$	Forecasted transactions	¥92,292	¥—	¥609
Interest rate swaps:				
Fixed rate payment, floating rate receipt	Long-term debt	1,000	—	(3)

Thousands of U.S. Dollars				
December 31, 2015	Hedged item	Contract amount	Contract amount due after one year	Fair value
Foreign currency forward contracts:				
Buying U.S. \$	Forecasted transactions	\$ 3,565	\$—	\$ 50
Selling U.S. \$	Forecasted transactions	71,387	—	1,558
<b>Total</b>		<b>\$74,952</b>	<b>\$—</b>	<b>\$1,608</b>

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.

## 18. Contingent liabilities

The Group's contingent liabilities as of December 31, 2015 are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Trade notes discounted	¥ 471	\$ 3,905
Trade notes endorsed	19	158
Guarantees and similar items of bank loans	1,844	15,289

## 19. Comprehensive income

The components of other comprehensive income for the fiscal years ended December 31, 2015 and 2014 were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Unrealized gain (loss) on available-for-sale securities:			
Gains (losses) arising during the year	¥19,632	¥ (1,363)	\$162,773
Reclassification adjustments to profit or loss	—	—	—
Amount before income tax effect	19,632	(1,363)	162,773
Income tax effect	(5,632)	602	(46,696)
<b>Total</b>	<b>¥14,000</b>	<b>¥ (761)</b>	<b>\$116,077</b>
Deferred (loss) gain on derivatives under hedge accounting:			
(Losses) gains arising during the year	¥ (359)	¥ 650	\$ (2,977)
Reclassification adjustments to profit or loss	(56)	(33)	(464)
Amount before income tax effect	(415)	617	(3,441)
Income tax effect	152	(219)	1,260
<b>Total</b>	<b>¥ (263)</b>	<b>¥ 398</b>	<b>\$ (2,181)</b>
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ (9,140)	¥42,492	\$ (75,781)
Reclassification adjustments to profit or loss	(182)	(90)	(1,509)
Amount before income tax effect	(9,322)	42,402	(77,290)
Income tax effect	—	—	—
<b>Total</b>	<b>¥ (9,322)</b>	<b>¥42,402</b>	<b>\$ (77,290)</b>
Defined retirement benefit plans			
Adjustments arising during the year	¥ (3,609)	¥ 3,633	\$ (29,923)
Reclassification adjustments to profit or loss	(6,387)	(5,155)	(52,956)
Amount before income tax effect	(9,996)	(1,522)	(82,879)
Income tax effect	3,761	546	31,183
<b>Total</b>	<b>¥ (6,235)</b>	<b>¥ (976)</b>	<b>\$ (51,696)</b>
Share of other comprehensive income in associates:			
(Losses) gains arising during the year	¥ (6,617)	¥12,347	\$ (54,863)
Reclassification	(965)	(20)	(8,001)
<b>Total</b>	<b>¥ (7,582)</b>	<b>¥12,327</b>	<b>\$ (62,864)</b>
<b>Total other comprehensive (loss) income</b>	<b>¥ (9,402)</b>	<b>¥53,390</b>	<b>\$ (77,954)</b>

## 20. Cash flow information

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

### December 31, 2015

Details of assets and liabilities and price and payments for the acquisition of Avanir Pharmaceuticals, Inc., Biocentury, S.L.U. and four other companies are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Current assets	¥ 43,352	\$ 359,440
Non-current assets	301,411	2,499,055
Goodwill	167,591	1,389,528
Current liabilities	(12,664)	(105,000)
Long-term liabilities	(77,032)	(638,686)
Cost of purchase of investments in subsidiaries	422,658	3,504,337
Cash and cash equivalents of newly consolidated companies	(30,131)	(249,822)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	¥392,527	\$ 3,254,515

### December 31, 2014

Details of assets and liabilities and price and payments for the acquisition of Jasmine Comercio de Productos Alimenticios LTDA, FoodState, Inc., Higashiyama Film Co., Ltd. and one other company are as follows:

	Millions of Yen
Current assets	¥10,820
Non-current assets	6,925
Goodwill	22,815
Current liabilities	(6,916)
Long-term liabilities	(1,410)
Minority interests	(553)
Cost of purchase of investments in subsidiaries	31,681
Account payables included in the acquisition price	(3,345)
Cash and cash equivalents of newly consolidated companies	(1,632)
Purchase of investments in subsidiaries resulting in change in scope of consolidation	¥26,704

(2) Nonmonetary transactions

There were no material nonmonetary transactions requiring disclosure for the fiscal years ended December 31, 2015 and 2014.

## 21. Net income per share

The reconciliation of the differences between basic and diluted net income per share (EPS) for the fiscal years ended December 31, 2015 and 2014 was as follows:

December 31, 2015	Millions of Yen	Thousands of shares	Yen	U.S.Dollars
	Net income	Weighted-average shares		EPS
Basic EPS				
Net income available to common shareholders	¥84,054	541,839	¥155.13	\$1.29
Effect of dilutive securities				
Warrants	—	—		
Stock options	—	42		
Diluted EPS				
Net income for computation	¥84,054	541,881	¥155.11	\$1.29

December 31, 2014	Millions of Yen	Thousands of shares	Yen
	Net income	Weighted-average shares	EPS
Basic EPS			
Net income available to common shareholders	¥143,112	541,679	¥264.20
Effect of dilutive securities			
Warrants	—	—	
Stock options	—	160	
Diluted EPS			
Net income for computation	¥143,112	541,839	¥264.12

## 22. Subsequent events

### Appropriation of retained earnings

The following appropriation of retained earnings as of December 31, 2015 was approved at a meeting of the Company's board of directors held on February 12, 2016:

	Millions of Yen	Thousands of U.S. Dollars
Year-end cash dividends, ¥50.0 (US\$0.41) per share	¥27,092	\$224,625

## 23. Segment information

### For the fiscal years ended December 31, 2015 and 2014

#### 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 its business into four reporting segments: "Pharmaceuticals," "Nutraceuticals," "Consumer products" and "Other" businesses.

The Group defines the reporting segments as follows:

- "Pharmaceuticals" comprises research and development, manufacturing and sales of prescription drugs as well as clinical nutrition, including intravenous solutions.
- "Nutraceuticals" comprises manufacturing and sales of functional foods, over-the-counter drugs and supplements.
- "Consumer products" comprises manufacturing and sales of mineral water, beverages, and food products.
- "Other" operations encompass logistics, warehousing, manufacturing and sales of chemical products, evaluation systems for LED displays and spectroanalysis devices.

#### 2. Calculation methods for sales, profit (loss), assets, and other items

Methods of accounting procedures for reported business segments are the same as those for statements in Note 2.

"Summary of significant accounting policies." Income of reported segments is the figure based on operating income. Intersegment profits or transfers are based on market price.

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

Millions of Yen							
December 31, 2015	Reportable segment					Reconciliations (Note 1)	Consolidated (Note 4)
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Total		
<b>Sales</b>							
Sales to external customers	¥ 971,843	¥321,555	¥ 42,875	¥108,954	¥1,445,227	¥ —	¥1,445,227
Intersegment sales and transfers	—	8,648	325	36,239	45,212	(45,212)	—
<b>Total</b>	<b>971,843</b>	<b>330,203</b>	<b>43,200</b>	<b>145,193</b>	<b>1,490,439</b>	<b>(45,212)</b>	<b>1,445,227</b>
<b>Segment profit (loss)</b>	<b>156,814</b>	<b>31,267</b>	<b>(3,315)</b>	<b>5,894</b>	<b>190,660</b>	<b>(38,823)</b>	<b>151,837</b>
<b>Segment assets</b>	<b>1,286,233</b>	<b>271,233</b>	<b>147,531</b>	<b>172,774</b>	<b>1,877,771</b>	<b>650,739</b>	<b>2,528,510</b>
<b>Other:</b>							
Depreciation (Note 2)	35,826	11,415	1,102	4,760	53,103	4,383	57,486
Amortization of goodwill	11,161	2,227	58	545	13,991	—	13,991
Investment in equity-method affiliates	27,658	13,076	114,707	20,119	175,560	—	175,560
Increase in property, plant and equipment and intangible assets (Note 3)	488,118	19,030	5,971	8,018	521,137	2,726	523,863

Millions of Yen							
December 31, 2014	Reportable segment					Reconciliations (Note 1)	Consolidated (Note 4)
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Total		
<b>Sales</b>							
Sales to external customers	¥883,519	¥232,741	¥ 34,372	¥ 73,666	¥1,224,298	¥ —	¥1,224,298
Intersegment sales and transfers	—	5,415	158	28,581	34,154	(34,154)	—
<b>Total</b>	<b>883,519</b>	<b>238,156</b>	<b>34,530</b>	<b>102,247</b>	<b>1,258,452</b>	<b>(34,154)</b>	<b>1,224,298</b>
<b>Segment profit (loss)</b>	<b>204,792</b>	<b>21,867</b>	<b>(1,404)</b>	<b>5,534</b>	<b>230,789</b>	<b>(34,260)</b>	<b>196,529</b>
<b>Segment assets</b>	<b>887,093</b>	<b>274,340</b>	<b>147,984</b>	<b>176,626</b>	<b>1,486,043</b>	<b>692,141</b>	<b>2,178,184</b>
<b>Other:</b>							
Depreciation (Note 2)	25,692	8,111	999	3,507	38,309	3,416	41,725
Amortization of goodwill	2,167	1,469	45	132	3,813	—	3,813
Investment in equity-method affiliates	32,823	13,509	118,131	18,922	183,385	—	183,385
Increase in property, plant and equipment and intangible assets (Note 3)	31,658	31,874	2,868	18,608	85,008	3,218	88,226

Thousands of U.S. Dollars							
December 31, 2015	Reportable segment					Reconciliations (Note 1)	Consolidated (Note 4)
	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Total		
<b>Sales</b>							
Sales to external customers	\$8,057,732	\$2,666,072	\$ 355,485	\$ 903,358	\$11,982,647	\$ —	\$11,982,647
Intersegment sales and transfers	—	71,703	2,694	300,464	374,861	(374,861)	—
<b>Total</b>	<b>8,057,732</b>	<b>2,737,775</b>	<b>358,179</b>	<b>1,203,822</b>	<b>12,357,508</b>	<b>(374,861)</b>	<b>11,982,647</b>
<b>Segment profit (loss)</b>	<b>1,300,174</b>	<b>259,241</b>	<b>(27,485)</b>	<b>48,868</b>	<b>1,580,798</b>	<b>(321,889)</b>	<b>1,258,909</b>
<b>Segment assets</b>	<b>10,664,398</b>	<b>2,248,843</b>	<b>1,223,207</b>	<b>1,432,502</b>	<b>15,568,950</b>	<b>5,395,398</b>	<b>20,964,348</b>
<b>Other:</b>							
Depreciation (Note 2)	297,040	94,644	9,137	39,466	440,287	36,340	476,627
Amortization of goodwill	92,538	18,464	481	4,519	116,002	—	116,002
Investment in equity-method affiliates	229,318	108,416	951,057	166,810	1,455,601	—	1,455,601
Increase in property, plant and equipment and intangible assets (Note 3)	4,047,077	157,781	49,507	66,479	4,320,844	22,602	4,343,446

Note 1: Reconciliations are as follows:

Segment profit (loss)	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Intersegment eliminations	¥628	¥116	\$5,207
Corporate expenses*	(39,451)	(34,376)	(327,096)
<b>Total</b>	<b>¥(38,823)</b>	<b>¥(34,260)</b>	<b>\$(321,889)</b>

\*Corporate expenses include costs associated with indirect departments of the Company and certain consolidated subsidiaries' headquarters.

Segment assets	Millions of Yen		Thousands of U.S. Dollars
	2015.12	2014.12	2015.12
Intersegment eliminations	¥(8,267)	¥(8,307)	\$(68,543)
Corporate assets*	659,007	700,448	5,463,949
<b>Total</b>	<b>¥650,740</b>	<b>¥692,141</b>	<b>\$5,395,406</b>

\*Corporate assets include assets associated with the Company and certain consolidated subsidiaries' headquarters and research institutes.

Note 2: Depreciation consists of depreciation of property, plant and equipment, intangible assets and prepaid expenses long-term for common properties of the Company and certain consolidated subsidiaries' headquarters.  
 Note 3: Increase in property, plant and equipment and intangible assets consists of capital expenditures for common properties of the Company and certain consolidated subsidiaries' headquarters and research institutes.  
 Note 4: Consolidated segment profit (loss) is adjusted to the operating income in the consolidated statement of income.

4. Information about products and services

Millions of Yen			
2015.12	ABILIFY	Other	Total
Sales to external customers	¥347,470	¥1,097,757	¥1,445,227

Millions of Yen			
2014.12	ABILIFY	Other	Total
Sales to external customers	¥507,393	¥716,905	¥1,224,298

Thousands of U.S. Dollars			
2015.12	ABILIFY	Other	Total
Sales to external customers	\$2,880,939	\$9,101,708	\$11,982,647

5. Information about geographical areas

(1) Sales

Millions of Yen			
2015.12			
Japan	North America	Other	Total
¥639,475	¥465,561	¥340,191	¥1,445,227

Millions of Yen			
2014.12			
Japan	North America	Other	Total
¥467,327	¥545,329	¥211,642	¥1,224,298

Thousands of U.S. Dollars			
2015.12			
Japan	North America	Other	Total
\$5,302,006	\$3,860,053	\$2,820,588	\$11,982,647

(2) Property, plant and equipment

Millions of Yen			
2015.12			
Japan	North America	Other	Total
¥234,302	¥49,790	¥72,330	¥356,422

Millions of Yen			
2014.12			
Japan	North America	Other	Total
¥230,338	¥42,950	¥71,496	¥344,784

Thousands of U.S. Dollars			
2015.12			
Japan	North America	Other	Total
\$1,942,632	\$412,818	\$599,711	\$2,955,161

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

6. Information about major customers

Data for 2015.12 is omitted as no individual external customer had a transaction volume with the Group which exceeded 10% of consolidated sales.

Millions of Yen		
2014.12	Net sales	Segment
McKesson Corporation	¥167,228	Pharmaceuticals
Cardinal Health Inc.	126,234	Pharmaceuticals

7. Information about impairment losses on fixed assets

Millions of Yen						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Impairment losses	¥14,781	¥293	¥—	¥3,624	¥122	¥18,820

Millions of Yen						
2014.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Impairment losses	¥4,896	¥176	¥79	¥1	¥226	¥5,378

Thousands of U.S. Dollars						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Impairment losses	\$122,552	\$2,429	\$—	\$30,047	\$1,012	\$156,040

## Notes to Consolidated Financial Statements

Otsuka Holdings and its Consolidated Subsidiaries

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

Millions of Yen						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	¥ 11,161	¥ 2,227	¥ 58	¥ 545	—	¥ 13,991
Balance	191,075	36,579	356	5,962	—	233,972

Millions of Yen						
2014.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	¥ 2,167	¥ 1,469	¥ 45	¥ 132	—	¥ 3,813
Balance	43,314	39,292	417	10,139	—	93,162

Thousands of U.S. Dollars						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	\$ 92,538	\$ 18,464	\$ 481	\$ 4,519	—	\$ 116,002
Balance	1,584,238	303,283	2,952	49,432	—	1,939,905

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

Millions of Yen						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	¥ 2,208	—	—	¥ 256	—	¥ 2,464
Balance	15,590	—	—	1,637	—	17,227

Millions of Yen						
2014.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	¥ 1,656	—	—	¥ 192	—	¥ 1,848
Balance	17,798	—	—	1,893	—	19,691

Thousands of U.S. Dollars						
2015.12	Pharmaceuticals	Nutraceuticals	Consumer products	Other	Elimination/Corporate	Total
Amortization	\$ 18,307	—	—	\$ 2,122	—	\$ 20,429
Balance	129,260	—	—	13,572	—	142,832

### 10. Information about gain on negative goodwill

Information about gain on negative goodwill is omitted due to immateriality.

# Group Companies

\* Including unconsolidated subsidiaries

## [ Japan ]

- Otsuka Holdings Co., Ltd.
- Otsuka Wellness Vending Co., Ltd.
- Otsuka Pharmaceutical Co., Ltd.
- Otsuka Ridge Co., Ltd.
- Otsuka Electronics Co., Ltd.
- Nippon Pharmaceutical Chemicals Co., Ltd.
- Chuo Electronic Measurement Co., Ltd.
- Okayama Taiho Pharmaceutical Co., Ltd.
- Taiho Pharmaceutical Co., Ltd.
- Otsuka Naruto Development, Inc.
- Otsuka Pharmaceutical Factory, Inc.
- Otsuka Techno Corporation
- J.O. Pharma Co., Ltd.
- EN Otsuka Pharmaceutical Co., Ltd.
- Otsuka Warehouse Co., Ltd.
- Otsuka Packaging Industries Co., Ltd.
- Dairin Integrated Transportation Co., Ltd.
- HAIESU Service Co., Ltd.
- Otsuka Chemical Co., Ltd.
- ILS, Inc.
- Otsuka Turftech Co., Ltd.
- Otsuka Foods Co., Ltd.
- Otsuka Furniture Manufacturing and Sales Co., Ltd.
- Otsuka Ohmi Ceramics Co., Ltd.
- Higashiyama Film Co., Ltd.
- Otsuka Chilled Foods Co., Ltd.
- Otsuka-MGC Chemical Company, Inc.
- Otsuka Medical Devices Co., Ltd.
- KISCO Co., Ltd.
- JIMRO Co., Ltd.
- NEOS Corporation
- Earth Chemical Co., Ltd.
- Earth Environmental Service Co., Ltd.
- Nichiban Co., Ltd.
- Heartful Kawauchi Co., Ltd.
- Naruto Cruise Service Co., Ltd.
- Agri Best Co., Ltd.
- Lilium Otsuka Co., Ltd.
- Ribomic, Inc.
- Kitasato-Otsuka Biomedical Assay Laboratories Co., Ltd.
- Tokushima Vortis Co., Ltd.
- Bean Stalk Snow Co., Ltd.
- Naruto Salt Mfg. Co., Ltd.
- Tokushima Air Terminal Building Co., Ltd.
- Big Bell Co., Ltd.
- Awa Union Transportation Co., Ltd.
- Marukita Furniture Center
- Yoshino Farm
- Earth Biochemical Co., Ltd.

## [ North America ]

- Otsuka Maryland Medicinal Laboratories, Inc.
- Otsuka Global Insurance, Inc.
- Otsuka Pharmaceutical Development & Commercialization, Inc.
- Otsuka America, Inc.
- Otsuka America Pharmaceutical, Inc.
- Pharmavite LLC
- Ridge Vineyards, Inc.
- Cambridge Isotope Laboratories, Inc.
- Crystal Geyser Water Company
- Astex Pharmaceuticals, Inc.
- Pharmavite Direct LLC
- FoodState, Inc.

- Avanir Pharmaceuticals, Inc.
- Avanir Acquisition Corporation
- Avanir Holding Company
- Xenex Biosciences
- CIL Isotope Separations, LLC
- Membrane Receptor Technologies, LLC
- Taiho Oncology, Inc.
- Otsuka Chemical America, Inc.
- Otsuka Canada Pharmaceutical, Inc.
- 2768691 Canada, Inc.
- Crystal Geyser Brand Holdings, LLC
- CG Roxane LLC
- ODH, Inc.
- Oncomembrane, Inc.
- ReCor Medical Inc.
- Galenea Corp.

## [ South America ]

- Jasmine Comercio de Produtos Alimentícios LTDA
- Otsuka Chemical do Brasil Ltda.

## [ Europe ]

- Astex Therapeutics, Ltd.
- Otsuka Europe Development & Commercialisation, Ltd.
- Otsuka Pharmaceuticals (U.K.) Ltd.
- Otsuka Pharmaceutical Europe Ltd.
- Nutrition & Santé Benelux S.A.
- Nardobel SAS
- Nutrition & Santé SAS
- Nutrition & Nature SAS
- Laboratoires Dietetique et Santé SAS
- Otsuka Pharmaceutical France SAS
- Euriso-Top SAS
- Kisco International SAS
- Otsuka Pharma GmbH
- Otsuka Frankfurt Research Institute GmbH
- Advanced Biochemical Compounds GmbH
- Cambridge Isotope Laboratories (Europe) GmbH
- Euriso-Top GmbH
- Interpharma Praha, a.s.
- Biocentury Portugal, Unipessoal Lda.
- Otsuka Pharmaceutical, S.A.
- Biocentury, S.L.U.
- Nutrition & Santé Iberia SL
- Hebron S.A.
- Trocellen Iberica S.A.
- Otsuka Pharma Scandinavia AB
- Nutrinat AG
- Otsuka Pharmaceutical (Switzerland) GmbH
- Nutrition & Santé Italia SpA
- Otsuka Pharmaceutical Italy S.r.l.
- ALMA S.A.
- Taiho Pharma Europe, Limited
- Otsuka Novel Products GmbH
- Otsuka S.A.
- Era Endoscopy S.r.l.

## [ Oceania ]

- Diatranz Otsuka Limited
- Otsuka Australia Pharmaceutical Pty Ltd

## [ Asia and Middle East and others ]

- Otsuka Pharmaceutical (H.K.) Ltd.
- Otsuka Beijing Research Institute

- Sichuan Otsuka Pharmaceutical Co., Ltd.
- Zhejiang Otsuka Pharmaceutical Co., Ltd.
- Otsuka (China) Investment Co., Ltd.
- Pharmavite (Shanghai) Business Information Consultancy Co., Ltd.
- Tianjin Otsuka Beverage Co., Ltd.
- Otsuka Sims (Guangdong) Beverage Co., Ltd.
- Suzhou Otsuka Pharmaceutical Co., Ltd.
- Shanghai Otsuka Foods Co., Ltd.
- Zhangjiagang Otsuka Chemical Co., Ltd.
- Higashiyama (Shanghai) Function Film Co., Ltd.
- Taiwan Otsuka Pharmaceutical Co., Ltd.
- Korea OIAA Co., Ltd.
- Otsuka Electronics Korea Co., Ltd.
- Korea Otsuka Pharmaceutical Co., Ltd.
- KOC Co., Ltd.
- Otsuka (Philippines) Pharmaceutical, Inc.
- P.T. Amerta Indah Otsuka
- P.T. Otsuka Indonesia
- P.T. Widatra Bhakti
- P.T. Otsuka Jaya Indah
- P.T. Merapi Utama Pharma
- P.T. Lautan Otsuka Chemical
- Claris Otsuka Private Limited
- Otsuka Chemical (India) Private Limited
- Abdi Ibrahim Otsuka Ilac San. Ve Tic. A.S. / Abdi Ibrahim Otsuka Pharmaceutical Company
- Giant Harvest, Ltd.
- Egypt Otsuka Pharmaceutical Co., S.A.E.
- Otsuka Pakistan Ltd.
- China Otsuka Pharmaceutical Co., Ltd.
- Guangdong Otsuka Pharmaceutical Co., Ltd.
- VV Food & Beverage Co., Ltd.
- Shanghai MicroPort Medical (Group) Co., Ltd.
- King Car Otsuka Co., Ltd.
- Dong-A Otsuka Co., Ltd.
- Thai Otsuka Pharmaceutical Co., Ltd.
- MicroPort Scientific Corporation
- Hangzhou Linan Kangle Pharmaceutical Co., Ltd.
- Otsuka Shanghai Research Institute
- Otsuka Electronics Shanghai Co., Ltd.
- Otsuka Electronics (Suzhou) Co., Ltd.
- Taiho Pharmaceutical of Beijing Co., Ltd.
- Leshan Otsuka Techno Co., Ltd.
- Nanjing Otsuka Techbond Techno Co., Ltd.
- Changzhou Otsuka Econ Techno Co., Ltd.
- Otsuka Material Science & Technology (Shanghai) Co., Ltd.
- NOBLE SKILL LIMITED
- Otsuka South China Precision Instruments (Shenzhen) Co., Ltd.
- Otsuka (Shanghai) Foods Safety Research & Development Co., Ltd.
- Dalian Otsuka Furniture Co., Ltd.
- Xiamen United Medical Instruments Co., Ltd.
- Otsuka Tech Electronics Co., Ltd.
- Higashiyama Film (Taiwan) Tech Co., Ltd.
- Higashiyama Film Korea Co., Ltd.
- Otsuka Thang Nutrition Co., Ltd.
- Otsuka OPV Joint Stock Company
- Otsuka Saha Asia Research Co., Ltd.
- Taiho Pharma Singapore Pte. Ltd.
- Achieva Medical Limited
- Otsuka Import Export, LLC
- Otsuka Trading Africa Co., S.A.E.
- Otsuka Ateco Pharma Egypt (Ahmed Zaghloul & Partners) Limited Partnership

● : Consolidated subsidiaries and affiliates accounted for by the equity method (as of December 31, 2015)

# Shareholder Information

(As of December 31, 2015)

Number of shares authorized	1,600,000,000
Number of shares issued	557,835,617
Number of shareholders	54,839

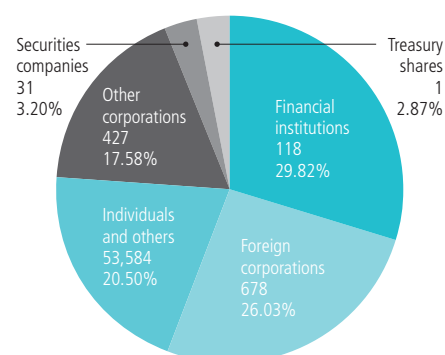
## Principal shareholders

Name	Number of shares held (Thousands)	Shareholding ratio (%)
The Nomura Trust and Banking Co., Ltd. Otsuka Founders Shareholding Fund Trust Account	62,038	11.44
Otsuka Estate Limited	22,891	4.22
Japan Trustee Services Bank, Ltd. (trust account)	16,378	3.02
The Master Trust Bank of Japan, Ltd. (trust account)	15,613	2.88
Otsuka Group Employee Shareholding Fund	15,181	2.80
The Awa Bank, Ltd.	10,970	2.02
GOLDMAN SACHS & CO. REG	7,844	1.44
Otsuka Asset Co., Ltd.	7,380	1.36
STATE STREET BANK WEST CLIENT - TREATY 505234	7,303	1.34
THE BANK OF NEW YORK MELLON SA/NV 10	7,140	1.31

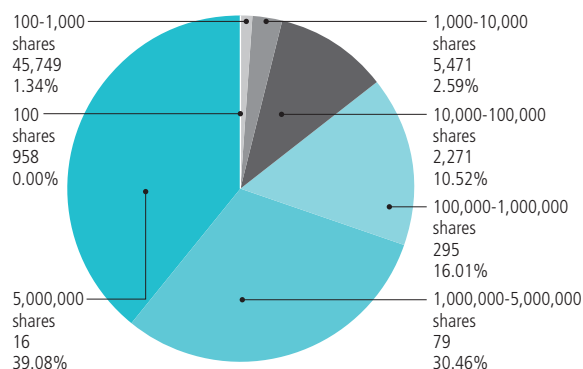
Notes:  
 1. Number of shares held is rounded down to the nearest thousand.  
 2. The Company holds treasury stock (15,985,891 shares) but is excluded from the principal shareholders listed above.  
 3. Shareholding ratio is calculated after treasury stock is deducted.

## Stock distribution

Distribution of Shares by Type of Shareholder



Distribution of Shares by Number of Shares Owned



### 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>

### Disclaimer

This annual report summarizes the operating and financial results of Otsuka Holdings Co., Ltd. and its subsidiaries and affiliates for fiscal 2015 (January 1, 2015 to December 31, 2015). It also includes information regarding selected material events which occurred between January 1, 2016 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 the report. Actual results may therefore differ due to the risks and uncertainties that may affect Otsuka Group operations.

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



