

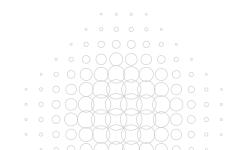
## ANNUAL REPORT 2016

For the year ended December 31, 2016



Otsuka-people creating new products for better health worldwide





Otsuka Holdings Co., Ltd.

## Corporate Philosophy

# Otsuka-people creating new products for better health worldwide



In keeping with this corporate philosophy and the Otsuka mottos of Jissho (Actualization) and Sozosei (Creativity), the Otsuka Group strives to utilize its unique resources 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.



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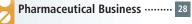




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#### Disclaimer

#### Precautions Regarding Forward-Looking Statements

This annual report summarizes the operating and financial results of Otsuka Holdings Co., Ltd. and its subsidiaries and affiliates for fiscal 2016 (January 1, 2016 to December 31, 2016). It also includes information regarding selected material events which occurred between January 1, 2017 and the date of publication. The report contains forward-looking statements pertaining to plans, projections, strategies, and prospects for the Otsuka group of companies. 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.

#### Medical information

In this annual report, a unified brand name is used when a product has different brand names in different countries or regions for the sake of readability. Therefore, these products may not be available in all countries, or may be available under different brand names, for different indications, in different dosages and strengths. Please note that the information regarding pharmaceutical products (including products under development) is not intended as any kind of advertising, promotion or medical advice.



### **Business Model**

## "Total Healthcare" with two core businesses

The Otsuka group of companies 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.



FY2014 to FY2018

Three years to establish a structure and system to be a world-class global healthcare company

Five years to establish a broad business portfolio for sustainable growth

## Otsuka's Goal

## To become an indispensable contributor to people's health worldwide

The Otsuka group of companies operates with the aim of becoming an indispensable contributor to people's health worldwide, fulfilling on our corporate philosophy in every activity. We endeavor to create and provide the universal value of improving health worldwide.

**Corporate Philosophy** 

# Otsuka-people creating new products for better health worldwide

N<sup>th</sup> Medium-Term Management Plan



The Otsuka group of companies is engaged in four main businesses: the pharmaceutical business, the nutraceutical business, the consumer products business, and other business. \*The figures below refer to sales to external customers.

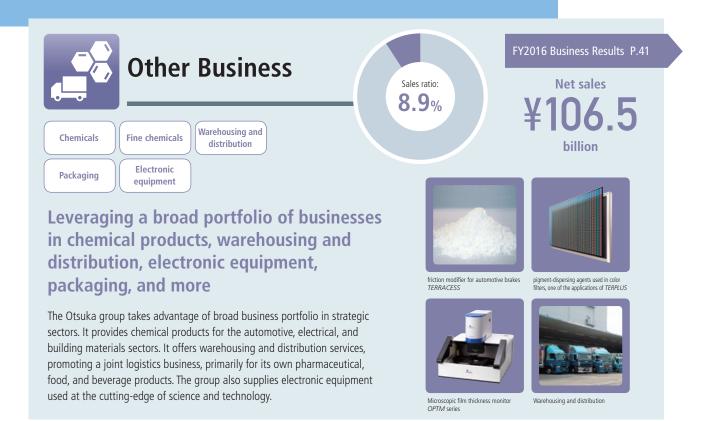


## Otsuka-people creating new products





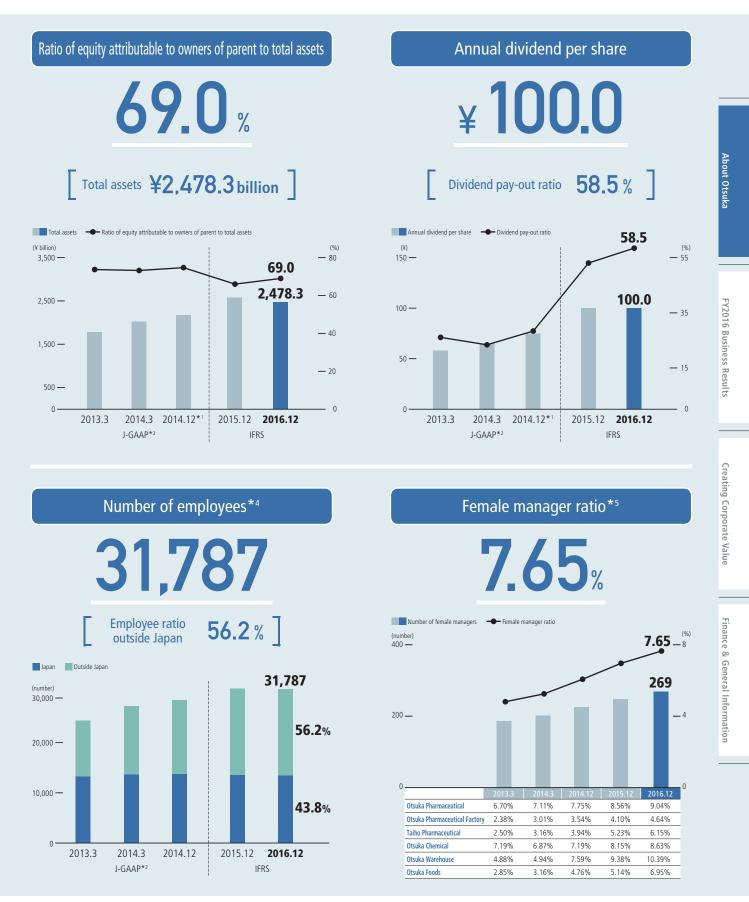
## for better health worldwide



## **Financial and Non-Financial Highlights**

With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.





\*1 Due to a change in the consolidated fiscal year, fiscal 2014 (ended December 31, 2014) was a transitional period covering the nine months from April 1 to December 31, 2014.

\*2 Japanese Generally Accepted Accounting Principles \*3 'net income' under J-GAAP \*4 Number of employees at Otsuka Holdings and its subsidiaries. \*5 Figures of six operating companies in Japan.



## Fulfilling our corporate philosophy by bringing next-generation healthcare to the world



The environment in which business decision makers operate has changed dramatically in recent years, with surges in both political and economic turbulence. In 2016 alone, we saw major changes – a majority of voters in the UK chose to exit the EU, the results of the U.S. presidential election defied all expectations, and emerging economies cooled off.

Meanwhile, the healthcare field is witnessing wide-ranging efforts to brake medical cost increases, as countries attempt to slow the increase of entitlement spending driven by aging demographics. Drug prices are being reduced, and generic drugs are being promoted and becoming widely used.

In light of this, the Otsuka group of companies faces the challenge of navigating this historical turning point, ensuring continued success amid large-scale structural changes across economies, societies, and the political world. No matter how the world changes, however, people everywhere still want to lead healthy lives. That's why the Otsuka group provides not only products for the diagnosis and treatment of diseases, but also a wide range of nutraceutical products that help to maintain and improve everyday health. In a changing world, we believe that our change-embracing group of companies is more relevant than ever.

The Otsuka group has an unwavering commitment to our corporate philosophy—"Otsuka-people creating new products for better health worldwide." Building on that solid foundation, we are utilizing the group's unique resources and skills to develop differentiated scientific solutions in ways that only Otsuka can. We continue to deliver products that meet the universal aspiration of people around the world to be healthy. Going forward, we will leverage the group's creative value to benefit society with a high sense of ethics and transparent corporate management. In everything we do, our aim is to become an indispensable contributor to people's health worldwide.

We invite all of our stakeholders to count on the Otsuka group to deliver the total healthcare of the future. I and my 45,000 colleagues deeply appreciate your ongoing support for the Otsuka group.

Tatsuo Higuchi President and Representative Director, CEO

Salanof Leguli

#### 09

Finance & General Information

## **Review of Fiscal 2016**

The loss of exclusivity for the antipsychotic agent **ABILIFY**, which has been a major driver of the group's earnings, resulted in lower sales and profit in fiscal 2016 compared to the previous year. However, we have succeeded in steadily implementing the priority measures of our Second Medium-Term Management Plan, which has prioritized a diversification of our revenue structure. Accordingly, we experienced promising growth performance in recently launched drugs and steady progress of the candidate compounds that constitute the core of our R&D investment. Operating margin in the nutraceutical business also improved. All in all, the performance we achieved in 2016 sets the stage for the sustainable growth we expect going forward.

In the pharmaceutical business, we have several products driving sustainable growth: the antipsychotic ABILIFY MAINTENA

(aripiprazole), a long-acting injectable of **ABILIFY**; the new antipsychotic agent **REXULTI** (brexpiprazole); the vasopressin receptor-2 antagonist Samsca/JINARC (tolvaptan); and the anticancer agent LONSURF (trifluridine/tipiracil). These Otsuka-originated global products and several new drugs for the Japanese market achieved sales far surpassing full-year forecasts, confirming our growth trajectory.

We also made strong progress in the R&D pipeline. We filed for approval of the additional indication of bipolar I disorder for ABILIFY MAINTENA in the U.S. and for approval of the indication of schizophrenia for brexpiprazole in Japan and Europe. We saw steady progress in a Phase III trial in the U.S. for tolvaptan for the treatment of autosomal dominant polycystic kidney disease (ADPKD). A global, Phase I trial for TAS-102 in the treatment of gastric cancer was also initiated. We are pleased to see these late-stage compounds moving forward according to plan.

#### R&D Activities—Pharmaceutical Business P.24

In the nutraceutical business, we launched several products that provide new value to consumers, including **POCARI SWEAT JELLY** in our POCARI SWEAT brand, Calorie Mate JELLY in our Calorie Mate brand, and SOYJOY Crispy in our SOYJOY brand. These new products are contributing to growing earnings in Japan, including from the original products in these brands. Outside Japan, the vitamin business operated by Pharmavite performed well in the U.S., and in Europe, earnings at Nutrition & Santé increased. In Asia, POCARI SWEAT, Oronamin C Drink, and the nutrient drink Tiovita went on sale in more countries, accelerating the global expansion of our nutraceutical business.

#### Group of products proving our drug discovery capability



ABILIFY MAINTENA, achieving growth, contributing to overall category growth for long-acting injectable atypical antipsychotics



JINARC. the first and only treatment for ADPKD in the world



REXULTI, a new antipsychotic agent

with unique pharmacological effects

LONSURF, achieving rapid growth as a treatment for refractory metastatic colorectal cancer due to its highly evaluated safety and efficacy

POCARI SWEAT JELLY, providing new product value as an edible water replenishment

creating new markets



SOYJOY Crispy, a new taste sensation from a delicious soybean bar

Calorie Mate JELLY, a jelly that makes it easy to take the balanced nutrition provided by the Calorie Mate brand

Products based on scientific evidence that are



Nature Made (vitamins, minerals and supplements) achieving steady growth in the U.S



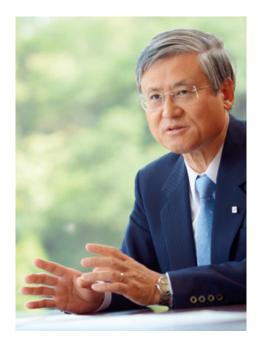
## **Achieving Sustainable Growth**

#### Progress on the Second Medium-Term Management Plan and our future course

The Otsuka group of companies is striving to deliver on its Second Medium-Term Management Plan, which covers the five years from fiscal 2014 through fiscal 2018. Continuing investments and structural reforms lie at the core of the plan. Building on that, the plan aims to continue the identification and expansion of business opportunities and to diversify the revenue structure. These goals are being achieved through the reinforcement of our therapeutic franchises in the pharmaceutical business and the pursuit of reform, restructuring and growth in the nutraceutical business.

Progress in fiscal 2016, the third year of the plan, was generally consistent with the initial plan, and we were encouraged by the progress on diversification of our revenue structure. In the pharmaceutical business, we quickly enhanced values of the global products that are our growth drivers, and strengthened our product pipeline in core areas as well as acquiring new technology. In the nutraceutical business, we achieved a target of over 10% operating profit margin. These indicators of strong performance made fiscal 2016 a meaningful year.

In fiscal 2017, we will take these steps even further as we approach the end of the plan. We will strive to continue increasing corporate value by proactively seizing business opportunities that will help deliver growth, which we expect to really take off in fiscal 2019.



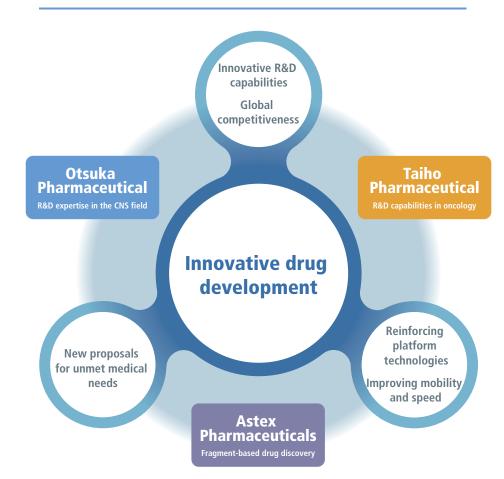
#### Maximizing the value of new drugs

We expect ABILIFY MAINTENA, REXULTI, and Samsca/JINARC to be our key growth drivers in the medium and long term. These and other products are generating growth that outpaces our initial forecasts. In fiscal 2018, the final year of this plan, we are targeting ¥430 billion in sales of these new drugs. With this goal in mind, in fiscal 2017 we plan to aggressively pursue measures such as filing for approval of new drugs and additional indications and expanding the geographical reach of our marketing. Moreover, in order to further accelerate growth after the plan, we will focus on developing and enhancing products that can contribute to revenue. These include Avanir Pharmaceuticals' products and pipeline candidates, as well as vadadustat for renal anemia which we are developing with Akebia Therapeutics. In addition, centanafadine for attention deficit/hyperactivity disorder (ADHD) has become another pipeline candidate after acquisition of Neurovance in March 2017. We will proactively work to introduce external resources that can generate synergy with our corporate value.



\*New drugs in Japan: Products launched in Japan since 2009 or due to be launched (excluding products included in global products and next-generation products)

#### Innovation from a new research and development approach that leverages the Otsuka group's strengths



#### R&D investment-Strengthening the pipeline in core fields

The basic emphasis of the Otsuka group's pharmaceutical business is to create new markets and contribute to patients around the world with unique and innovative products. The areas of the central nervous system (CNS), including psychiatry and neurology, and oncology are key priorities for the group, and we have eagerly taken up the challenge to tackle unmet medical needs in these fields. We are maximizing product values and working hard to move pipeline projects more quickly to market. In fiscal 2017 and beyond, we will further expand investment in R&D, looking to increase the number of late-phase projects significantly in the lead up to our next medium-term management plan.

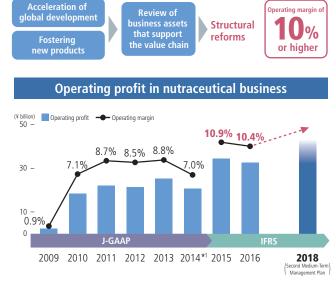
The capability to create new drugs is essential for sustainable growth. Needless to say, we will continue to put emphasis on the group's own basic research, but we will also consider and pursue collaboration with external partners as a viable option to acquire technologies and expertise we do not possess. We feel this approach has great potential for creating synergies with our own resources and spurring growth and innovation.

Thus far, our major operating companies have all generated their own innovations through advanced drug discovery research activities. Otsuka Pharmaceutical is strong in the areas of psychiatry and neurology (central nervous system/CNS). Taiho Pharmaceutical has advanced expertise in the oncology field. Astex Pharmaceuticals is a pioneer in fragment-based drug discovery, joining the group in 2013. We have continued to integrate and link the R&D platforms and original technologies that these companies have built up on their own. This has enabled us to build today's seamless structure, with its remarkable competitive advantages. These group companies also independently pursue open innovation as they aim to build networks and improve the quality and speed of drug discovery research by gaining access to the latest research and technology.

We will continue to strengthen our platform technologies in order to create innovative therapeutic drugs that address unmet medical needs.

## Pursuing structural reforms and improving earnings in the nutraceutical business

One of the core elements of the medium-term management plan is structural reforms and evolution to achieve growth in the nutraceutical business. Accordingly, we are accelerating the global expansion of the business and focusing on new product development. We have also reviewed the business assets that support the value chain, and successfully achieved, earlier than scheduled, an operating profit margin of over 10%. Keying off this milestone, we will continue to build a business structure that can deliver sustainable growth.



\*1 Unaudited indicators for same financial period (January-December 2014)

## Accelerating global expansion and fostering new products

The nutraceutical business generated 54% of total sales from outside Japan in fiscal 2016, up from 48% in fiscal 2013.\*<sup>2</sup> This growth in sales outside Japan made a significant contribution to the performance of this business and drove improved operating margins. Functional foods by Nutrition & Santé in Europe and **Nature Made** vitamins and supplements by Pharmavite in the U.S. were the major factors in this growth. In Asia, the pace of growth is slowing due to the impact of weaker economies and changes in the market environment following the launch of competing products. Despite these factors, sales grew steadily. The Otsuka group will continue to work to grow the nutraceutical business outside Japan, while also actively investing resources to make the most of the market in Japan and reinforce the foundation of the business.

\*2 Calculated based on J-GAAP

Sales of nutraceutical business by area\*3

#### \*3 Sales to external customers based on J-GAAP

#### Reviewing the business assets that support the value chain

In order to grow and strengthen the nutraceutical business even more, the Otsuka group is carrying out a fundamental review of its business assets across the value chain, from R&D to production, marketing and distribution, and is working to optimize the product supply system and maximize the value provided.

In this business, the Otsuka group's basic strategy is to identify yet-to-be-imagined needs, develop pathbreaking products that create customer value based on the appeal of healthy life expectancy, leverage Otsuka's knowledge and know-how at each stage in the value chain, and invest in building strong brand equity for the long term. By effectively executing this strategy, we can establish a business structure that can deliver steady growth, ensuring our nutraceutical business fulfills its role in our total healthcare mission.

## The Otsuka Group's Strengths

## Passing on Otsuka's corporate philosophy and culture: The core drivers of growth

Ever since its foundation in 1921, the Otsuka group of companies has consistently done businesses according to the corporate philosophy "Otsuka-people creating new products for better health worldwide." The group has a heritage of innovation, unrestricted by the "conventional wisdom" or the dictates of the day. We go to great lengths to ensure that all of our employees worldwide share this commitment to our corporate philosophy. We work to ensure it broadly penetrates the organization and system and ask everyone to treat it as an unchanging golden rule governing our daily business activities. Today, we have become a corporate group with over ¥1 trillion in annual consolidated sales, but our adventurous spirit as a trailblazer is undiminished. In daily work settings, individual employees are encouraged to ask questions like, "Is this innovative? Does it help people? Can it be supplied around the world?" The answers to these questions help fuel our quest to create new value that transcends all preconceived notions.



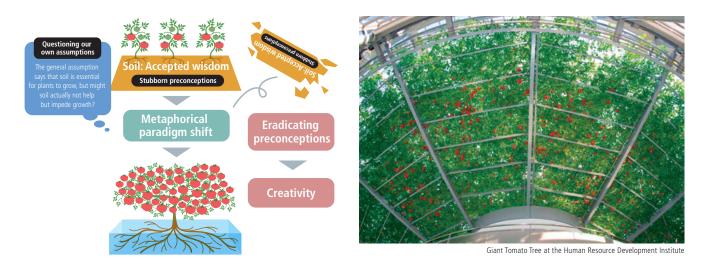
Corporate philosophy shared by group companies worldwide

#### Paradigm shifts enhance creativity

The Human Resource Development Institute, the training center for employees located in Tokushima, Japan, where Otsuka was founded, has several monuments depicting *Sozosei* (creativity), the concept at the basis of the group's corporate philosophy. One of them is the Giant Tomato Tree, which grows countless red tomatoes. Its leaves almost completely cover the ceiling in the entrance hall of the institute.

A tomato plant grown in soil using conventional cultivation methods would not be able to grow such a large quantity of tomatoes. However, we metaphorically shifted the paradigm, based on the fact that soil-based cultivation places an upper limit on a tomato plant's growth. We abandoned the preconception that, "since tomato plants are grown in soil, soil is the essential medium." This enabled us to set the tomato plant's roots free, using hydroponic cultivation. As a result, the roots grew prolifically and absorbed more water and nutrition, and the plant produced over 10,000 tomatoes. By removing the impediments to the fecundity of the tomato tree, we were able to achieve results that surpass what anyone thought possible.

This tree reminds us that if we free ourselves from norms, we can unlock our full potential. This kind of metaphorical paradigm shift, illustrated by the tomato plant, is what fosters the Otsuka group's creativity and drives the invention of innovative products and services. Not only that, our human resource development policy is based on the conviction that eliminating rigid thinking bound by "conventional wisdom" is certain to spur employees' talents and creativity.



#### Ryukan godo, Jissho and Sozosei

Throughout our history, the leaders of the Otsuka group have stressed the need for *Ryukan godo* (by sweat we recognize the way), *Jissho* (actualization) and *Sozosei* (creativity.) *Ryukan godo* means to discover the core substance of something through hard work and practice. In the words of our founder, Busaburo Otsuka, he said, "I do not mean to sweat physically but mean something much deeper – an internal, spiritual sweat that arises from a blazing passion for one's work and a realization of the road one should travel to achieve it". This reflects our belief that understanding what customers value and what their true needs are—and then demonstrating this understanding in

action—are the most important functions of company employees. *Jissho* is defined as "self-actualization through achievement, completion and the discovery of truth." *Sozosei*, or "creativity," epitomizes the Otsuka group's corporate culture. Throughout the value chain, from R&D to marketing, we pursue our own approach, ignoring imitations. This is what allows us to develop innovative ideas and transform them into pathbreaking products, as well as design optimal business structures.

The Otsuka group's current successes are built on the legacies of the Otsuka leaders of the past, who all passionately practiced these three concepts. We are committed to passing this corporate culture on to the next generation.



Ryukan godo A calligraphic work by Otsuka founder, Busaburo Otsuka

## Never-give-up R&D: On-site management and *Jissho*



#### A diuretic that excretes only water

The Otsuka group's researchers meet with doctors and researchers from around the world. This gives researchers the opportunity to examine and sense for themselves how their research actually helps in healthcare. Research on vasopressin (an anti-diuretic hormone) began following a request from a medical practitioner for a diuretic that excretes only water. At that time, diuretics also increased the excretion of electrolytes, which was problematic. Otsuka Pharmaceutical began this drug discovery project in 1983. In 2009, the company succeeded in launching *Samsca*, a revolutionary diuretic that causes the excretion of water only—26 years after development began. Subsequently, we obtained an additional indication for the treatment of autosomal dominant polycystic kidney disease (ADPKD), which was previously untreatable. With this move, *Samsca/JINARC* grew into a core product that will support the group's future growth. Most companies would have decided to end a project long before 26 years, but the Otsuka group's strong sense of mission about actualizing its corporate philosophy—"Otsuka-people creating new products for better health worldwide"—ensured that we kept on with research and development. The result is a groundbreaking treatment for intractable kidney disease.

#### Renewed determination after failure

Many development failures lie behind every successful drug, but they are not a waste as long as they are not seen as the end point. The Otsuka group has the corporate culture of identifying the reasons behind failures to make the most of them as an asset, and has a process for exploiting mistakes effectively as catalysts for the future. **ABILIFY** is a typical example of this. In the 1970s, researchers working on the development of an antihistamine that would not cause drowsiness noticed that, unexpectedly, a rat during the experiment fell asleep. Normally, the experiment would have been deemed a failure and would have ended. However, the researchers thought that the fact that the rat had fallen asleep was evidence of the compound's effect on the central nervous system, and followed up on this pharmacological effect. After 30 years of difficult research, the antipsychotic **ABILIFY** was finally launched in 2002.

Schizophrenia is thought to occur when excessive amounts of dopamine and other neurotransmitters are released in the brain. At the time, many antipsychotic agents designed to inhibit the actions of dopamine were on the market, but patients and medical professionals continued to be frustrated by their side effects, such as tremors, muscle rigidity, and oversedation. ABILIFY works as a partial agonist to dopamine D<sub>2</sub> receptors, acting as an antagonist when excessive amounts of dopamine are released in the brain and as an agonist when only small amounts of dopamine are released. This function as a dopamine system stabilizer gives it a completely new mechanism of action. ABILIFY is the result of research that began with failures in an experiment, and developed into a major product that has contributed greatly to the group's growth. ABILIFY has also yielded other assets that will drive the group's future growth: ABILIFY MAINTENA, a long-acting injectable, which is effective for a month with a single monthly dose; and **REXULTI**, a new antipsychotic agent that builds on the impressive drug profile of **ABILIFY**.



FIBE-MINI, a food for

specified health uses

## Creating products based on scientific evidence and painstakingly cultivating brands

#### Epoch-Making POCARI SWEAT

The Otsuka group's nutraceutical products are produced using a flexible approach to research that is not held back by preconceptions related to preferences and convenience. **POCARI SWEAT**, which has now become a mainstay product for the group, did not initially take off in the market when launched in 1980, because it was so completely unprecedented.

**POCARI SWEAT** was the result of thoroughgoing research into how guickly the water and electrolytes (ions) lost from the body when perspiring could be restored, which provided solid scientific evidence. Given this, Otsuka group leaders decided that it was more important to give consumers an understanding of the product's value and its concept than merely to maximize sales. To do this, sales staffs visited venues where people perspired and asked them to try **POCARI SWEAT**, all the while talking about the importance of replenishing water and ions. Almost 40 years after it was first launched, we continue to provide a variety of information in order to convey the product concept to consumers. These efforts have paid off, and the POCARI SWEAT brand is now popular in 20 countries and regions<sup>\*1</sup> around the world.

POCARI SWEAT when introduced was revolutionary as a consumer product based on scientific evidence, for its basic concept, and for its unique product value. Promoting such product features to consumers enabled us to create an entirely new market by identifying and fulfilling yet-to-be-imagined needs. We attribute this success to the many employees who put Ryukan godo, Jissho and Sozosei into practice and a management system that strategizes business operations across a long time frame.

\*1: as of March 31. 2017

POCARI SWEAT at first launch

## A product lineup that creates new values and new categories

POCARI SWEAT is by no means the only Otsuka consumer product that succeeded in creating a new market through offering unique product value. FIBE-MINI is another pathbreaking product in which we turned our own attention, and later consumer attention, to dietary fiber, which at the time was not thought to benefit health. Calorie Mate created a new market for balanced nutritional foods. In 2014, we also launched EQUELLE, a food product containing equol, derived from soybeans, after 18 years of research and development on women's health. These category-defining products were all created due to the paradigmshifting thought processes that our corporate philosophy makes possible.

The Saga Nutraceuticals Research Institute, established in 1984, played a pivotal role in the development of these nutraceutical products. Opened as Japan's first private research institute for exercise and nutrition, the institute identifies, in multi-layered research, the science behind how nutritional products maintain and enhance health. Today, the institute continues to create new research-based products, new values and new categories.







Calorie Mate, a balanced nutritional food

EOUELLE, a product containing soybean-derived equol



Saga Nutraceuticals Research Institute

Artificial environmental control room at the research institute





History

P.22

## **Human Resources and Diversity**

#### Developing human resources and promoting total health

Human resources are key assets for a company and the main source of corporate growth. Developing human resources to lead the next generation is just as important as medium- and long-term capital investment. Without doing so, we cannot sustain the group's growth into the future or increase its values as a creative, innovative company. The Otsuka group undertakes a wide range of human resource development programs. These include opportunities to study abroad and opportunities for employees, together with management, to absorb the corporate culture and to share values that emphasize creativity. We strive to foster human resources that can excel globally.

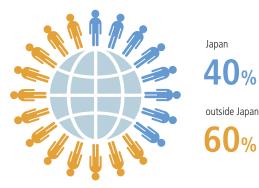
The mental and physical health of each employee is also essential to achieve sustainable growth. That's why we believe it very important to provide a work environment that seeks to sustain and enhance the health of all group employees and their families. The group issued the Otsuka Group Declaration on Health in April 2017. In line with it, we strive to create a work environment where employees can work comfortably and safely and exercise their full abilities. Healthier employees help to create stronger corporate values.

#### Diversity initiatives

Across the Otsuka group companies, employees from many different backgrounds drive business growth. We recognize that a diverse workforce is essential to making an organization strong and flexible enough to adapt to environmental changes. We have respected diversity and sought to utilize diverse employees since the 1980s, when the concept of diversity was not yet in the social spotlight in Japan. At present, the Otsuka group has about 18,000 employees in Japan and 27,000 outside Japan.\*<sup>2</sup> By accepting and sharing different languages, cultures, backgrounds, experiences, and perspectives, we create a flexible and openminded corporate culture that can respond appropriately to the diversification of social needs and the globalization of our business.

We proactively seek to appoint female managers, while also holding diversity forums and running projects designed to give women opportunities to make the most of their skills. In addition, to support employees raising children, we have set up daycare centers in our business facilities and devised systems and programs to foster an ideal work-life balance.

In addition, we have taken measures that reflect the diversification of contemporary societies, such as promoting the hiring of persons with disabilities and expanding our rehiring system for senior employees. In this way, we are endeavoring to create a flexible organization able to draw out each individual's strengths.



Percentage of employees in Japan and outside Japan



Otsuka Pharmaceutical: BeanStalk Kids Center in Tokushima, Japan



Taiho Pharmaceutical: Sukusuku Nursery in Ibaraki, Japan

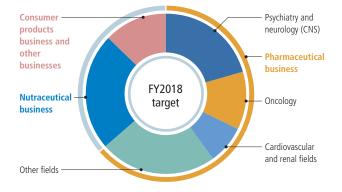
## **Strengths of Otsuka's Business Model**

#### Flexibility to adapt to changes in the business environment

The Otsuka group must be able to flexibly adapt to various business environments as it expands its business globally and in multiple directions. In the healthcare field in particular, Japan and other major countries are trying to lower and rationalize medical costs by reducing drug prices. Companies in this field will need to be able to respond to changes like these.

With the pharmaceutical business and nutraceutical business as the two mainstays of the Otsuka group, the Second Medium-Term Management Plan covers the five-year period in which the group will establish a truly diversified business portfolio. We are pursuing strategies aimed at expanding revenue sources in the conviction that we must build a foundation to generate revenue from broadbased businesses in order to adapt to changes such as drug price reductions. For instance, daily health management is a prerequisite to reducing medical costs, and the Otsuka group's health-

#### Diversification of sales structure under Second Medium-Term Management Plan



promoting nutraceutical products can make enormous contributions here.

At the same time, the group aims to contribute to healthcare optimization to address pressures across healthcare systems around the world to stem increases in medical costs. For example, in the case of schizophrenia, many patients have difficulty recognizing that they have this condition, and so often stop taking their medicine, leading to a relapse and a cycle of hospitalization and release—which means higher medical costs. We developed an innovative, long-acting injectable that only has to be given once a month, which helps to reduce patients' hospitalizations, the duration of their stays, and medical costs. In addition, we are developing tablets embedded with microchips—the world's first digital medicine—which can record and report the dosage taken. We are not only contributing to healthcare optimization with more sophisticated products; we also carry out research and development that will lead to value creation by providing solutions for issues that cannot be addressed with pharmaceuticals alone.

P.31 Otsuka's challenges

#### Growth through revenue diversification

While we can expect substantial returns when we succeed with our research and development in the pharmaceutical business and launch products onto the market, our earning contract sharply when the patents on drugs expire. This means that our pharmaceutical business is characterized by high risks and high returns. At the same time, it is difficult to expect the high profitability of the pharmaceutical business from the nutraceutical business. However, for the latter, once a brand is established, it can support a stable foundation of revenue over the long term. Trends have changed in the 90-plus years since our founding. Today, the pharmaceutical business is the primary driver of the group's growth, but just a short while ago sales were higher in the nutraceutical business. Moreover, without the profits generated by the nutraceutical business, the development of many therapeutic drugs that are currently growth drivers would not have been possible. As such, the diversification of the group's businesses has led to mutually reinforcing growth of a wide variety of products.



## **Corporate Governance**

Building and maintaining a solid governance system is essential to reliably deliver sustainable growth. The Otsuka group established its Corporate Governance Code in November 2015. The code lays out the group's approach to governance and its basic guidelines, both internally and externally. In addition, the group strives to increase corporate value in a manner that is sustainable over the medium- to longterm and to fulfill its mission as a company that is committed to the betterment of life. In February 2017, the group established the Corporate Governance Committee to serve as an advisory group for the Board of Directors, and further efforts to strengthen governance are underway. Moreover, the Otsuka group also established the Otsuka Group Global Code of Business Ethics as a guide for employees around the world to observe. The group also established a Global Anti-Corruption Policy that lays out its firm stance against corruption. These codes and policies require that each employee work with a high standard of ethics and fulfill responsibilities to stakeholders.

Currently, we have three outside directors and three outside Audit & Supervisory Board members to ensure transparent management. When selecting outside members, we give great weight to the candidates' knowledge about corporate management, as well as their wealth of experience and deep insight in various fields. The Board of Directors and Audit & Supervisory Board meetings have become rewarding forums for the exchange of frank opinions and views.

P.42 Corporate Governance

Corporate

philosophy

Products/

## Business Investments and Shareholder Returns

#### Prioritizing synergies and a long-term viewpoint in our investments

Two basic policies govern the Otsuka group's investments. First, in the case of an acquisition or alliance, we ask whether we can generate synergies by sharing corporate philosophy, human resources, products, and technology with the other company to create value. For example, in the case of Astex Pharmaceuticals, acquired in 2013, we let stakeholders know that the goal was to expand our portfolio in the areas of the central nervous system (psychiatry & neurology), and oncology, and make further advances in drug research by integrating that company's fragment-based drug discovery technology into our group assets.

The second policy is that we make investment decisions from a long-term perspective. We do not invest for short-term sales or merely to expand our scale. For the Otsuka group, the most important factor is not growth in our overall size, but the ability to attract resources through our competitive strengths so that these assets do not dry up. Even with small research seeds, we proactively invest our management resources in such technologies and ideas when we determine that they can lead to synergies with our knowledge and expertise and major growth. We will continue to make strategic investments from a long-term perspective in order to maximize corporate value.

#### Policy on shareholder returns

The Otsuka group views the distribution of profits to shareholders as a key management priority. Our basic policy regarding profit distribution is to provide stable dividends in line with income growth while securing the appropriate level of retained earnings necessary for long-term growth and proactive response to changes in the business environment.

We ask for your support of the Otsuka group as we strive to live up to our corporate philosophy in everything we do and work to deliver even greater sustainable growth and corporate value.

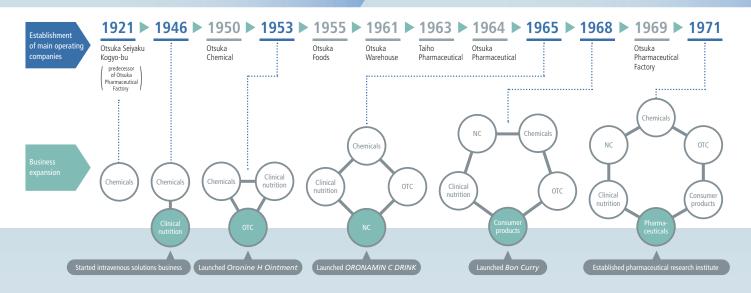


About Otsuka



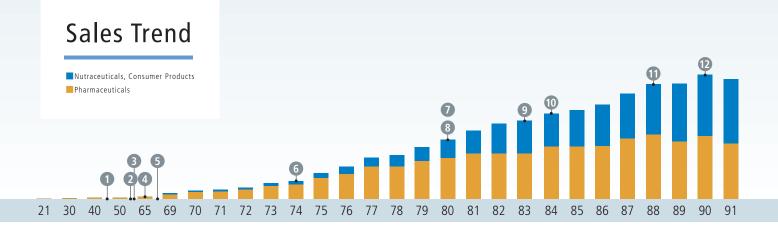
Foundation phase

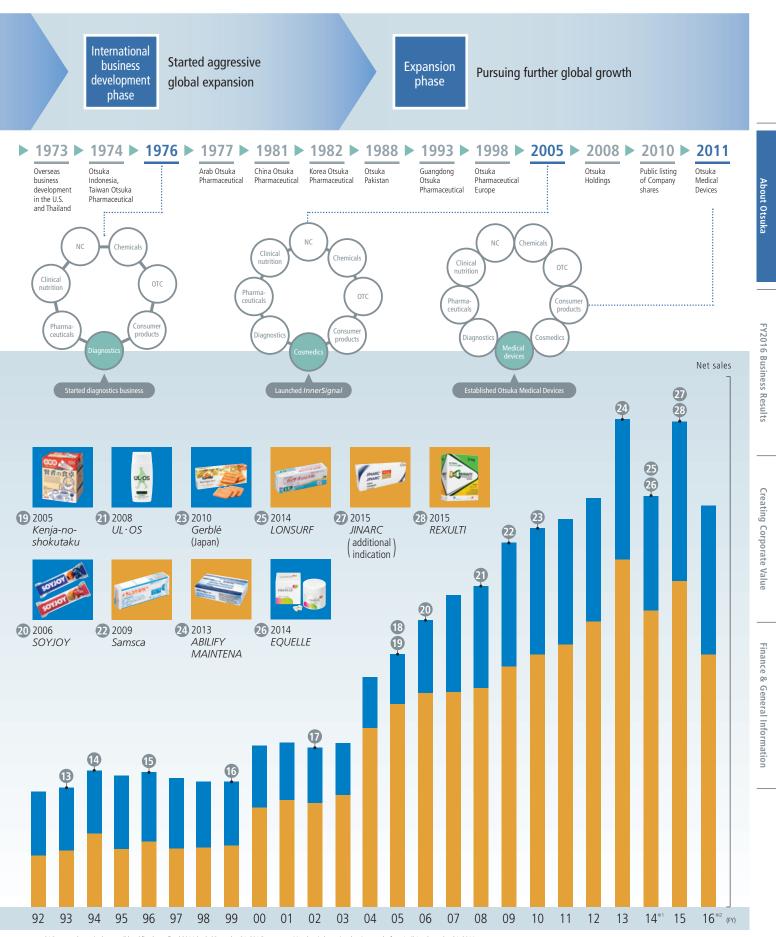
Started as a chemical raw material manufacturer in Naruto, Tokushima Prefecture, Japan Growth phase Opened the Tokushima Research Institute with the aim of in-house drug development. Numerous nutraceutical products opened up new markets, broadening the group's business



#### History of product development







\*1 Due to a change in the consolidated fiscal year, fiscal 2014 (ended December 31, 2014) was a transitional period covering the nine months from April 1 to December 31, 2014. \*2 With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.



Water and Electrolyte(Ion) Supplement Drink

## Product Development Story of POCARI SWEAT

— Leveraging Expertise in Intravenous Solutions Business –

The Otsuka group of companies was launched in 1921 in Tokushima as a manufacturer of raw chemical materials, making magnesium carbonate from bittern harvested from sea water. In 1946, the group began its intravenous solutions business in Japan, and later grew into Japan's leading company in this field. Using the expertise developed in this business, the group created *POCARI SWEAT*.



#### The idea came from medicine

POCARI SWEAT was developed more than 40 years ago. While an Otsuka researcher was on a business trip to Mexico, he experienced severe diarrhea and dehydration. The doctor handed him a carbonated beverage so that he could replenish his fluids. The researcher thought that it would be nice to have a drink perfectly formulated to give the human body the water it needs. Later, the researcher heard from his colleague that he had seen a doctor drinking an intravenous solution to rehydrate himself after finishing surgery. This was the moment of inspiration for a drinkable intravenous solution. With this idea, Otsuka researchers began to develop a rehydration beverage, pursuing the concept of a beverage for use in situations where people perspire that could replenish the water and electrolytes (ions) lost while sweating.

At that time, Japan's growing economy and prosperity were gradually raising people's interest in a healthy lifestyle. It became more common for people to spend their free time on sports or outdoors, and they were more likely to sweat during daily activities. However, Otsuka researchers directed their work at the development of a health beverage for everyone in various situations where people sweat, rather than on a sports drink, so that their product would appeal to more people.



#### **Challenging product development**

Through this work, the researchers found that there are different kinds of sweat. They also found that the concentration of salt in everyday sweat is lower than in sweat that occurs during sports activity. Based on these findings, the researchers came up with over 1,000 prototype beverages that recreated the components of everyday perspiration. However, the researchers were having trouble overcoming the saltiness and bitterness of the constituents of sweat. Developing a sweat replacement drink proved to be extremely difficult.

So they mixed a trial rehydration drink with a citrus powder juice that was being developed in the laboratory at the same time. Suddenly the bitter taste was gone, and a great-tasting beverage was born. Through this combination that no one had considered before, the development of this unprecedented drink took a big leap forward.

The research continued, and finally two test products were prepared: one with high and one with low sugar content. At that time sweet, juice-style beverages were the norm. Many researchers felt the low-sugar prototype was lacking something. However, since they were trying to develop a drink that tasted especially good after sweating, they tested it out themselves by climbing a mountain and drinking it after sweating. They realized that the lightly sweetened test product was easier to drink and went down smoothly. This determined the final flavor. It was the perfect time to attract consumers with a water and electrolyte replenishment beverage. With that, *POCARI SWEAT* was launched in 1980.

### Creating a new market

Although consumers have become more interested in health since *POCARI SWEAT* was first launched in the 1980s, the product was not accepted by consumers initially due to the new and unfamiliar concept of replenishing water and electrolytes. Therefore, Otsuka marketing staff visited a wide range of settings in which people become dehydrated in daily life and conducted awareness activities to communicate the concept and the importance of water and electrolyte replenishment; they gave out 30 million bottles of free samples in the first year of its launch alone. The promotion activity succeeded in communicating the value of *POCARI SWEAT* to customers, and a brand new market for ion (electrolyte) drinks had been created.

## For better health

The group works continuously to provide further evidence for ion (electrolyte) drinks, based on the unchanged concept of POCARI SWEAT.

The group aspires to contribute to better health for people all over the world by discovering scientific evidence for the effectiveness of water and ion replenishment in various situations—including for dehydration and winter dryness, after bathing, and to prevent traveller's thrombosis, \*—and by continuing to educate the public about the need for it.

\* Economy class syndrome

#### **POCARI SWEAT Column**

#### **Forbidden blue**

The iconic design for *POCARI SWEAT* depicts the essence of the product as a healthy drink replenishing water and ions. The colors —a very unusual choice in Japan's food and drink industry at that time— were selected for their cool and clean impression, conveying the blue of the ocean, the source of all life, and the white of its waters. The shape of the white wave symbolizes the curve of a graph comparing the absorption speed of plain water and *POCARI SWEAT*.





#### For the health of the planet

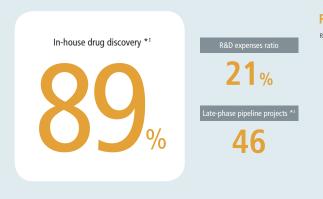
While the concept and design of the product have not changed, in 2007 Otsuka adopted a more environmentally friendly bottle to replace the 500ml plastic bottle. This reduced the polyethylene terephthalate resin content by about 30% (to 18.3 grams from 27 grams). This lightweight bottle is now used for *POCARI SWEAT Ion Water*, *Amino-Value*, and *energen*.

**Research and Development** 

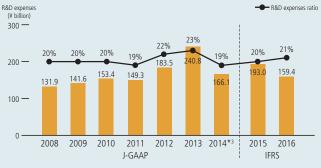
## R&D Activities— Pharmaceutical Business

The Otsuka group of companies takes a global approach to R&D, making steady R&D investments and leveraging the innovative creativity of each of its operating companies. R&D powers the group's aspiration to create new markets and contribute to unmet medical needs with innovative products.



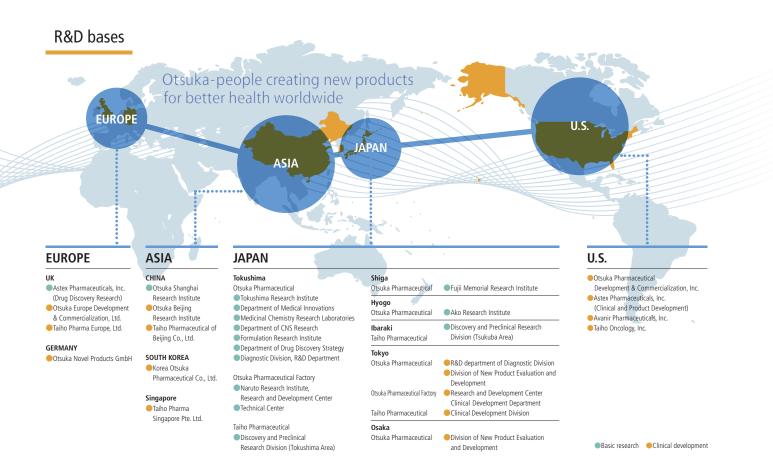


**R&D** expenses for pharmaceutical business



\*1: Ratio of in-house drug discovery projects in late-phase pipeline projects. \*2: Phase II or later stage of development as of December 31, 2016

\*3: Due to a change in the consolidated fiscal year, fiscal 2014 (ended December 31, 2014) was a transitional period covering the nine months from April 1 to December 31, 2014.



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## **Evolution of the Otsuka group's R&D**

## - R&D innovation leveraging our strengths -

The Otsuka group's drug discovery research is built upon a solid foundation that continues to drive originality and innovation. Otsuka Pharmaceutical leads its efforts in the field of the central nervous system and neurology, where it has particular strengths. Taiho Pharmaceutical exploits its own drug discovery technology platform mainly in oncology. Otsuka Pharmaceutical Factory spearheads the clinical nutrition business in Japan. Astex Pharmaceuticals, a pioneer in fragment-based drug discovery, and Avanir Pharmaceuticals, which is particularly skilled in development for neurology, have recently joined the Otsuka group. The group is coordinating and integrating the research platforms and ideas that these companies have each built. This will ensure that the Otsuka group's R&D continues to evolve, building a structure that yields new strengths and generates even more innovation.





#### Open innovation at the Otsuka group

The group companies pursue a unique approach to open innovation. Working together across specialties, they leverage their access to cutting-edge research and technologies to raise the quality and speed of drug discovery research.

Otsuka Pharmaceutical	<ul> <li>Research base established at the Kobe Biomedical Innovation Cluster (KBIC)</li> <li>RIKEN CDB-Otsuka Pharmaceutical Collaboration Center opened</li> <li>Comprehensive collaboration agreement signed with Osaka University Immunology Frontier Research Center (IFReC)</li> </ul>
Taiho Pharmaceutical	<ul> <li>Investment made and collaboration launched with Remiges BioPharma Fund (open innovation fund)</li> <li>Bio-venture company development support and collaboration promoted by establishing Taiho Ventures (U.S.)</li> </ul>
Astex Pharmaceuticals	<ul> <li>Collaboration in oncology field launched with the UK's National Cancer Research Institute, Newcastle University and Cancer Research UK</li> <li>Dementia consortium participation with Alzheimer's Research UK, MRC Technology and others</li> <li>Participation in drug discovery consortium of University of Cambridge</li> </ul>

## **Projects in Phase II and later stages**



## Central nervous system and neurology

In the area of central nervous system and neurology, one of Otsuka's core specialties, the knowledge and expertise the Company gained developing *ABILIFY* continue to drive multiple advances in innovation. The acquisition of Avanir Pharmaceuticals also marked the full entry of the Otsuka group into the neurology area. There are significant opportunities for growth in this area.

Code (Generic name) <brand name=""></brand>	Origin	Indication	Country / Region	Phase II	Stat Phase Ⅲ	tus Filed	Approved
OPC-14597 (aripiprazole) <abilify maintena=""> Dopamine partial agonist</abilify>	Otsuka Pharmaceutical	Bipolar I	US		Thuse m		Approved
		Major depressive disorder	EU				
OPC-34712 (brexpiprazole) < <i>REXULTI</i> >	Otsuka	Schizophrenia	JP, EU				
Dopamine partial agonist	Pharmaceutical	Agitation associated with dementia of the Alzheimer's type	US, EU				
		Posttraumatic stress disorder	US, EU				
ASC-01 (aripiprazole, sertraline) Dopamine partial agonist / Selective serotonin reuptake inhibitor	Otsuka Pharmaceutical	Major depressive disorder	JP, Asia				
AVP-923 (dextromethorphan, quinidine) NMDA receptor antagonist / Sigma-1 receptor agonist	Avanir Pharmaceuticals	Dyskinesia associated with Parkinson's disease	US				
AVP-786 (deuterium-modified dextromethorphan, quinidine)	Avanir Pharmaceuticals	Agitation associated with dementia of the Alzheimer's type	US, EU				
NMDA receptor antagonist / Serotonin and norepinephrine reuptake		Residual schizophrenia symptoms	US				
inhibitor / Sigma-1 receptor agonist		Disinhibition syndrome in neurodegenerative disorders	US				
EB-1020 (centanafadine) Norepinephrine, dopamine and serotonin reuptake inhibitor	Neurovance	Attention deficit hyperactivity disorder	US				
TAS-205 PGD synthase inhibitor	Taiho Pharmaceutical	Duchenne muscular dystrophy	JP				
Lu AA36143 (nalmefene) Opioid receptor antagonist	Lundbeck	Alcohol dependence	JP				



## Oncology

In the area of oncology, another of its core specialties, the Otsuka group is carrying out R&D on an entirely new type of anti-cancer drug using its expertise to respond to diversification in cancer treatments.

Code (Generic name) <brand name=""></brand>	Origin	Indication	Country / Region	Phase II	Stat Phase Ⅲ	us Filed	Approved
TAS-102 (trifluridine, tipiracil) < <i>LONSURF</i> >	Taiho	Colorectal cancer	Asia	Thuse II		Theu	Approved
Anti-cancer	Pharmaceutical	Gastric cancer	JP, US, EU				
TAS-118 (tegafur, gimeracil, oteracil, folinate)	Taiho	Pancreatic cancer	JP, Asia				
Anti-cancer (Anti-metabolite)	Pharmaceutical	Gastric cancer	JP, Asia				
<b>Pro-NETU (fosnetupitant)</b> NK <sub>1</sub> receptor antagonist	Helsinn Healthcare	Chemotherapy-induced nausea and vomiting	JP				
		Ovarian cancer	US, EU				
SGI-110 (guadecitabine) Anti-cancer	Astex Pharmaceuticals	Acute myeloid leukemia	JP, US, EU, Asia				
		Myelodysplastic syndrome	JP, US, EU, Asia				
AT13387 Anti-cancer (Molecular-targeted drug)	Astex Pharmaceuticals	Non-small cell lung cancer	US, EU				
AT7519 Anti-cancer (Molecular-targeted drug)	Astex Pharmaceuticals	Multiple myeloma	US				
ASTX727 Anti-cancer	Astex Pharmaceuticals	Myelodysplastic syndrome	US				
TAS-114 Anti-cancer (Anti-tumor effect enhancer)	Taiho Pharmaceutical	Non-small cell lung cancer	JP, US, EU				
TAS-115 Anti-cancer (Molecular-targeted drug)	Taiho Pharmaceutical	Prostate cancer	JP				
TAS-116 Anti-cancer (Molecular-targeted drug)	Taiho Pharmaceutical	Gastrointestinal stromal tumor	JP				
OCV-501 WT1 targeted cancer vaccine	Otsuka Pharmaceutical	Acute myeloid leukemia	JP, Asia				
OPC-12759 (rebamipide) Oral mucosal protectant/Mucosal healing agent	Otsuka Pharmaceutical	Stomatitis associated with cancer chemoradiotherapy	JP				



## Cardiovascular and renal system

Code (Generic name) <brand name=""></brand>	Origin Indication		Country /		Stat	us	
Category		Indication				Filed	Approved
		Hepatic edema	Asia				
		Autosomal dominant polycystic kidney disease	US				
	Otsuka Pharmaceutical	Autosonial dominant polycystic kidney disease	Asia				
OPC-41061 (tolvaptan) < <i>Samsca   JINARC</i> > V <sub>2</sub> -receptor antagonist		Cardiac edema	Asia				
		Carcinomatous edema	JP				
		Volume overload in hemodialysis	JP				
		Volume overload in peritoneal dialysis	JP				
AKB-6548 (vadadustat) HIF-prolyl hydroxylase inhibitor	Akebia Therapeutics	Anemia associated with chronic kidney disease	US				

## Other areas

Code (Generic name) <brand name=""></brand>	Origin	Indication	Country /	Status				
Category	Ongin	Region		Phase II	Phase 🎚	Filed	Approved	
YP-18 (tazobactam, piperacillin) <zosyn> Antibiotic agent</zosyn>	Taiho Pharmaceutical	Complicated skin and soft tissue infections (including diabetic foot infections)	JP					
TAS-303 Selective norepinephrine reuptake inhibitor	Taiho Pharmaceutical	Stress urinary incontinence	JP					
OPC-67683 (delamanid) <deltyba> Anti-tuberculosis agent</deltyba>	Otsuka Pharmaceutical	Multidrug-resistant tuberculosis	US					
OPC-12759E (rebamipide) < <i>Mucosta ophthalmic suspension</i> > Mucin-production enhancing agent	Otsuka Pharmaceutical	Dry eyes	JP					
<b>OPF-105 (glucose, electrolyte, amino acid, fat and multivitamin)</b> Protein and amino acid preparation	Otsuka Pharmaceutical Factory	Peripheral parenteral nutrition solution	JP					
OPA-15406 PDE4 inhibitor	Otsuka Pharmaceutical	Atopic dermatitis	JP					
<b>OPS-2071</b> New quinolone-based antibacterial agent	Otsuka Pharmaceutical	Clostridium difficile infection, enteric infection	JP, Asia					
C13-CAC (calcium (13C)) 13C-calcium carbonate breath test	Otsuka Pharmaceutical	Measurement of gastric acidity / In-vivo diagnostic agent	JP					
ODK-1003	Otsuka	Diagnosis for acute lymphoblastic leukemia / In-vitro diagnostic agent	JP					
WT1 mRNA RT-PCR Assay Kit	Pharmaceutical	Diagnosis for myelodysplastic syndrome / In-vitro diagnostic agent	Asia					

#### Drug development process

A new drug is brought to market after a process involving many stages that confirm its effectiveness and safety. Only then can the pharmaceutical company file for approval. Finally, the authorities review and approve the new medicine.







## **Pharmaceutical Business**

The group's pharmaceutical business addresses unmet medical needs with comprehensive healthcare solutions, from diagnosis through to the treatment of disease.

## **Overview of business in fiscal 2016**



In the pharmaceutical business, the loss of exclusivity for the antipsychotic agent *ABILIFY* in the U.S. and Europe and price reductions for several core products under the April 2016 Japanese National Health Insurance repricing to take account of market expansion resulted in a 22.6% reduction in segment net sales over the previous year to 753.0 billion yen and a 37.3% drop in operating profit to 92.0 billion yen in fiscal 2016. However, the segment showed growth in new products marketed globally, including *ABILIFY MAINTENA*, a long-acting injectable of *ABILIFY*, the new antipsychotic agent *REXULTI*, the V<sub>2</sub>-receptor antagonist *Samsca/JINARC*, and the anti-cancer agent *LONSURF*, as well as new drugs released in Japan. Their performance offset the decline in sales of *ABILIFY* and will lead to medium- and long-term growth.

In R&D activities, the Company made good progress with clinical trials and application filings for manufacturing and marketing authorization including approvals of *ONZETRA Xsail* for acute migraine treatment (U.S.), the combination ophthalmic solution *Mikeluna* for glaucoma and ocular hypertension treatment (Japan), and the anti-allergy drug *Bilanoa* (Japan).

#### Steady growth of new products

	Sa	les	
	FY2015 (¥ billion)	FY2016 (¥ billion)	Change
ABILIFY MAINTENA	40.4	57.2	+41.4%
REXULTI	4.6	29.8	+545.7%
Samsca/ JINARC	41.6	48.9	+17.5%
LONSURF	9.4	30.1	+220.6%
New drugs in Japan *2	87.0	105.4	+21.1%

\*2 Products launched in Japan since 2009 (excluding ABILIFY MAINTENA, Samsca/JINARC, and LONSURF).

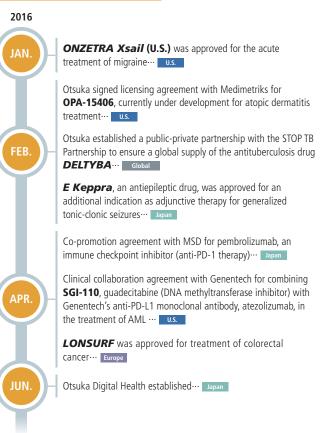
In the fiscal 2016 NHI drug price revisions, four of the group's drugs (*ABILIFY*, *E Keppra*, *Samsca* and *Abraxane*) were subject to repricing to reflect market expansion. Due to these impacts, the group's total NHI drug price revision rate exceeded the industry average. However, the group still has a high percentage of new drugs, and it will continue to contribute to the health of people worldwide through innovative products.

#### Otsuka group of companies' achievements in fiscal 2016

NHI drug price	NHI drug price revision rate (%)		2010	2012	2014 <sup>⊛³</sup>	2016
revision rate:	Otsuka group		(5.2)	(3.5)	(2.2)	(8.4)
(8.4%)	Industry average		(6.5)	(6.25)	(2.65)	(7.8)
(0.4%)			*	3 Includes provisio	n for increase in	consumption tax
Sales ratio of products receiving new drug development premium:	<sup>approx.</sup>	Sales ratio		approx. 17%		



## Key topics in 2016





SEP.

LONSURF, a treatment for colorectal cancer, launched in the UK··· Europe

Joint development agreement with NEC for **Pletaal Assist** System, a drug adherence support system for anti-stroke medication... Japan

Labeling update of antipsychotic drug **REXULTI** for maintenance treatment of schizophrenia... U.s.

Mikeluna combination ophthalmic solution was approved for treatment of glaucoma and ocular hypertension... Japan

Additional indication of antipsychotic agent **ABILIFY** for irritability associated with pediatric autistic spectrum was approved… Japan

ICLUSIG was approved for CML and Ph+ ALL... Japan

Anti-allergy drug **Bilanoa** was approved… Japan

Additional indication of bipolar I disorder was filed for antipsychotic agent **ABILIFY MAINTENA**... U.S.

Exclusive license agreement with Takara Bio for oncolytic virus HF10… Japan

Collaboration agreement with Akebia Therapeutics to develop and commercialize vadadustat, currently in development for the treatment of anemia... U.S.

## Fiscal 2017 initiatives

The group is endeavoring to strengthen the business foundation for sustainable growth beyond fiscal 2018. In the pharmaceutical business segment, the group will particularly emphasize the following measures in fiscal 2017:

- Maximize value of global products
- Aggressive R&D investment to achieve sustainable growth
- Enrich product pipelines and acquire new technologies in core therapeutic areas

In Japan, the Ministry of Health, Labour and Welfare sets the prices of prescription drugs. \*\* These official prices (drug prices) are regularly revised based on the results of a survey of actual market prices (the price at which the drugs are actually sold in hospitals and pharmacies). When these revisions are made, the official price can be reduced based on the discrepancy between the official price and the market price, and additional reductions can be made on the price of long-listed drugs\*<sup>5</sup> In addition, repricing to reflect market expansion is carried out for drugs whose sales have exceeded forecasts.\*<sup>6</sup> Accordingly, further reductions in drug prices can be made with the aim of cutting drug costs, while rules\*<sup>7</sup> that essentially maintain prices for new drugs are set with the aim of spuring the creation of new drugs.

\*4 The name and price of drugs that can be used in the medical insurance system are listed in the NHI Drug Price Standards, a list of drugs prepared by the Ministry of Health, Labour and Welfare.

<sup>&</sup>lt;sup>15</sup> The price of long-listed drugs for which generics have been available for five years or more is reduced based on the replacement rate by generics. The price of drugs with lower replacement rates tend to be reduced at a higher rate.
<sup>16</sup> Further drug price reduction is applied in the event that annual sales exceed the forecast by a certain degree.
<sup>17</sup> Pricing premium for the promotion of new drug development and the elimination/resolution of the based on the replacement rate by generics. The price of drugs with lower replacement rates tend to be reduced at a higher rate.
<sup>17</sup> Pricing premium for the promotion of new drug development and the elimination/resolution of rate based are price premium, which essentially maintains the drug price.







## **Central Nervous System and Neurology**

In the area of central nervous system (CNS) and neurology, the group continues its efforts to maximize the medical and commercial value of *ABILIFY MAINTENA* and *REXULTI*. The group is accelerating its strategy to expand operations in this field by integrating Otsuka Pharmaceutical's business strength in CNS and Avanir Pharmaceutical's expertise in the neurological area.

## **Main products**



#### Otsuka's business history in the central nervous system and neurology



### Unmet needs in CNS and neurology

The field of central nervous system and neurology encompasses a wide range of diseases, including schizophrenia, bipolar disorder, major depressive disorder, anxiety disorder that leads to behavioral and psychological problems, adjustment disorders that undermine the patient's social life and occupational and academic success, epilepsy, a chronic disorder of the cerebrum, and progressive neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease. Complex networks of cranial nerves contribute to these diseases, and, despite advances in science, we have not identified the cause or radical treatment for many diseases.

A World Health Organization (WHO) study showed that in many countries one out of every three people experiences a neuropsychiatric disorder in their lifetime. This statistic rises to one out of every two people in developed countries. Moreover, a survey conducted in the U.S. in 2010 on the number of years when people are prevented from living a healthy life due to disability (years lived with disability) found that mental and behavioral disorders and neurological disorders were the main factors, and occurred at a wide range of ages, from childhood and adolescence to old age.\* These disorders not only significantly harm the quality of life for people, but also result in massive losses for society.

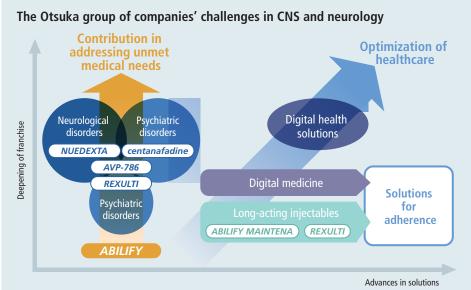
\* Source: JAMA. 2013;310(6):591-606. doi:10.1001/jama.2013.13805

## **Otsuka's challenges**

The Otsuka group of companies began its research in the CNS area in the 1980s. A quarter century of research resulted in the development of the antipsychotic agent *ABILIFY*, which was the world's first therapy to work by stabilizing the dopamine system. *ABILIFY* garnered high praise from medical fields. The group continued with a process of trial-and-error based on expertise achieved in the research and development and marketing of *ABILIFY*, ultimately creating *REXULTI*. With the addition of centanafadine, acquired from the U.S. firm Neurovance, Inc., in March 2017 and currently being developed as a treatment for attention deficit/hyperactivity disorder (ADHD), the group is pursuing a further deepening of its franchises in this field.

Moreover, in 2015 the group added *NUEDEXTA*, a treatment for pseudobulbar affect (PBA), and AVP-786 to its product portfolio with its purchase of the U.S.-based Avanir Pharmaceuticals. This heralds the group's full-scale entry into the neurology area. The group is taking up the challenge of solving unmet medical needs that have not seen effective medical treatments, such as Alzheimer's disease, a global problem that cannot be ignored, as well as PBA and disinhibition in neurodegenerative diseases.

Moreover, the group is providing solutions to optimize healthcare in the area of CNS and neurology to make comprehensive contributions to healthcare. As well as the launch of digital health solution businesses, these solutions include innovations to resolve the problem of medication adherence, for instance formulations such as long-acting injectable and medication measurement tools that integrate specialized knowledge and cutting-edge technology to create the world's first ingestible in-medication sensor to measure medication-taking patterns.











## **Oncology, Cancer Supportive Care**

In the area of oncology, the Otsuka group of companies operates in a wide range of sectors, from solid tumors and hematological cancers to cancer support care, with the aim of providing total cancer care. The in-house developed anti-cancer agent *LONSURF* has been recognized as one of the standard treatments for colorectal cancer and has expanded its sales regions. Moreover, Astex Pharmaceuticals, known for its fragment-based drug discovery technology, joined the group in 2013, and collaborates within the group in the development of innovative new drugs.

## **Main products**



## Unmet needs in oncology

According to WHO reports, there are 14 million new cancer cases every year around the world as of 2012, and as aging of the population continues, this is expected to increase to 22 million by 2022.

According to the National Cancer Institute, the five-year survival rate for cancer patients in the U.S. improved from less than 50% up until 1980 to 67% (data for 2007–2013), thanks to advances in diagnostic methods and medical treatment. However, this still means that approximately 30% of patients do not survive five years after diagnosis. At the same time, there are significant disparities in the survival rate and success rate for existing treatments depending on the type of cancer and age of the patient. Despite the astonishing advances in drugs, there are still many issues to resolve in the oncology field.

The Otsuka group of companies continues to take up the challenge of unmet medical needs and aims to make comprehensive contributions to cancer treatment.

#### Percentage Surviving 5 Years in the U.S. (2007–2013)



SEER Cancer Stat Facts: Cancer of Any Site. National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/statfacts/html/all.html The website of the National Cancer Institute (https://www.cancer.gov)

#### Otsuka's history in the oncology field





## Cardiovascular, Renal System

The V2-receptor antagonist Samsca/JINARC has contributed to healthcare as the world's only oral aquaretic agent which facilitates excretion of free water only without electrolyte loss. Samsca/JINARC is also growing steadily as the world's first treatment for the rare kidney condition autosomal dominant polycystic kidney disease (ADPKD). The group has designated this as a priority area, after CNS and neurology and the oncology, and is actively carrying out research and development.



## **Clinical nutrition**

The Otsuka group of companies has been operating in the intravenous solution business for over 70 years and leading the industry in Japan. Since the 1970s, the group has established intravenous solution manufacturing bases in eight countries overseas, \*2 primarily in Asia, in a business that capitalizes on its advanced technical skills. Going forward, the group will continue to develop high-value-added products that meet market needs around the world and contribute to global healthcare.

drugs and their side effects and in providing the right healthcare. The group provides companion diagnostic products in a wide range of fields such as digestive, respiratory and infectious diseases, cancer

The group's medical device business promotes medical devices globally with the aim of addressing unmet needs in the area of drug-resistant diseases and complex diseases by using a different approach from that

\*3 Companion diagnostics is a diagnostic test used to identify patients most likely to benefit from a particular therapy and to determine the optimal dose.

\*2 India, Indonesia, Egypt, Thailand, Taiwan, China, Pakistan, Vietnam

**Diagnostics** 

and the cardiovascular system.

Medical devices

of the therapeutic drug business.

# サムスカ 215

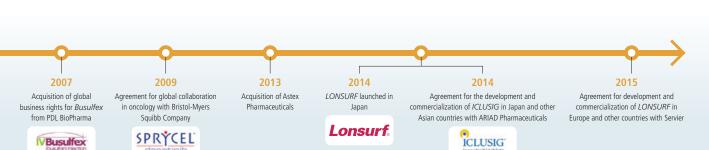


#### Aquaretic/ADPKD treatment Samsca/JINARC

Generic name	tolvaptan
Primary sales region	Japan, U.S., Europe, Asia
МоА	V <sup>2</sup> -receptor antagonist

FY 2016 sales (¥ billion)

Adacolumn Apheresis device for leukocyte adsorption



2016 sales

(¥ billion)

FY 2016 sales Υ. (¥ billion)

Companion diagnostics\*3 is extremely important in identifying the individual differences in the effect of

MAT. Reprinted with permission

Otsuka's share of intravenous

solution sales in Japan (2016)

UBIT <sup>13</sup>C-Urea breath agent for diagnosis of *H. pylori* infection







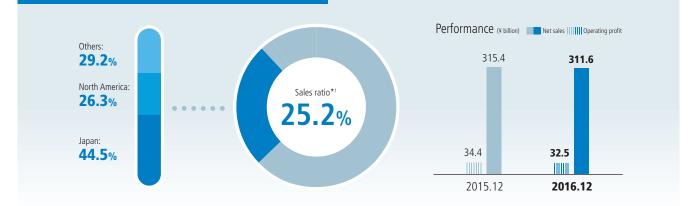


## **Nutraceutical Business**

The Otsuka group of companies provides innovative products based on scientific evidence that support and enhance people's daily health.



## Overview of business in fiscal 2016

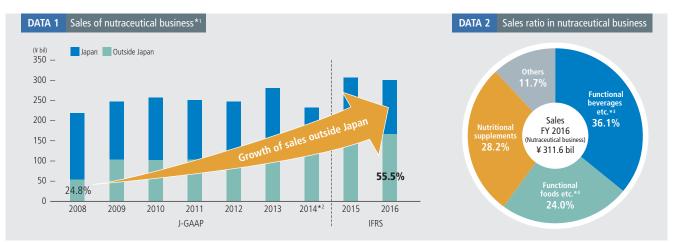


In the nutraceutical business, launching new products and strengthening sales promotion of mainstay products such as POCARI SWEAT, Calorie Mate, and SOYJOY contributed to consolidated performance in Japan. Outside Japan, sales of POCARI SWEAT fell short of the previous year due to weather conditions and the effect of competing products in Indonesia. However, Nature Made vitamins and supplements by Pharmavite in the U.S. and gluten-free products and organic soy products from nutritional and health food brands such as Gerblé, which are manufactured and sold primarily in Europe by Nutrition & Santé, achieved growth in sales.

Overall, net sales in the nutraceutical business in fiscal 2016 underperformed the previous year, impacted by the appreciation of the yen. Higher sales growth outside Japan, however, made a substantial contribution to the performance of this business and helped to improve profit margins. DATA 1, 2

Research and development activities focused on developing new products, based on the concept of extending healthy life expectancy.

In December 2016, the Otsuka group began a joint project involving collaboration among industry, government, and academia. This new initiative with the Japan Sport Council (JSC) aims to promote sports medicine and sports science and to further strengthen international competitiveness.



\*1 Sales to external customers

\*2 Due to a change in the consolidated fiscal year. fiscal 2014 (ended December 31, 2014) was a transitional period covering the nine months from April 1 to December 31, 2014 \*3 POCARI SWEAT, ORONAMIN C, Tiovita, Fibe-Mini \*4 Nutrition & Santé products, Calorie Mate, SOYJOY



## Key topics in 2016





NOV

DEC



**POCARI SWEAT** POCARI SWEAT ION WATER Powder (for 750ml) launched

**ORONAMIN C DRINK, POCARI SWEAT** Received the Good Design Long Life Design Award 2016

Awarded as "Best Communicator" and won "Top Runner Award" for third consecutive year at the Heatstroke Prevention Communication Project Hitosuzumi Awards 2016

### EQUOL

Relationship between PMS/PMDD\*<sup>s</sup> and production status of soy isoflavone metabolite equol presented at the Japan Society for Menopause and Women's Health

Start of a joint project with the Japan Sports Council (JSC) to promote sports medicine and science and strengthen international competitiveness

\*5 PMS stands for Premenstrual Syndrome and PMDD for Premenstrual Dysphoric Disorder

### Cooperative projects with prefectural and metropolitan governments

Otsuka Pharmaceutical collaborates with prefectural and metropolitan governments on activities aimed at utilizing Otsuka's unique knowledge and knowhow to maintain and promote the health of people in communities everywhere and extend healthy life expectancy. These activities focus on areas such as heat disorder countermeasures, the prevention of lifestyle diseases, sports promotion, food education, disaster prevention, and women's health. As of March 31, 2017, Otsuka Pharmaceutical had collaboration agreements with a total of 39 prefectural and metropolitan governments.

## Fiscal 2017 initiatives

The nutraceutical business has been making good progress on profitability and structural reform by executing the strategy of the 2nd Medium-Term Management Plan. The group is striving to maintain the stable profitability and expansion of the nutraceutical business, working on the following measures:

- Maintain over10% operating profit margin
- Increase operational efficiency through optimal resource allocation





## **Functional Beverages**

The group focuses investments for Pocari Sweat sales expansion in Asian countries, mainly Indonesia and China. In Japan, it is pursuing review of business assets through fostering new products for further growth.



### **POCARI SWEAT**

Year launched 1980

A functional drink that created a new market for ion drinks, which replenish the water and ions lost due to perspiration. Globally expanding, particularly in Asia, with the highest share of sports drinks in Indonesia.\*1 In 2016, POCARI SWEAT Jelly was launched.

DATA 3, 4



### Tiovita Drink Year launched 1964

A long-selling product originally launched more than half a century ago. This nutrient drink contains taurine, vitamins and carnitine chloride. Designated quasi-drug



### **ORONAMIN** C

Year launched 1965

A carbonated nutritional drink with vitamins.

### Solmack Plus

Year launched 1979

A gastrointestinal remedy for symptoms of nausea due to overeating or overdrinking. Second-class OTC drugs

## Amino-Value

Year launched 2003

A drink developed based on knowledge acquired through research into branched-chain amino acids (BCAA) in the clinical nutrition and sports nutrition fields.

Food with function claims\*2



\*1 Source: GlobalData plc. \*2 Amino-Value 4000 and Amino-Value Powder 8000

## Fibe-Mini

\*3 Lactic acid bacteria B240 is a strain isolated by Tokyo University of Agriculture, for which Otsuka Pharmaceutical has confirmed efficacy.

Renewal 2017 http://www.otsuka.co.jp/en/product/ fibemini/fibemini/ URL

A dietary fiber beverage approved as food for specified health uses helping to regulate gastrointestinal conditions. It was re-launched in 2017 to mark the 30th anniversary. Food for specified health use



BODY

AINT

### **OS-1**

Year launched 2001

An oral rehydration drink with a balance of electrolytes and glucose, based on the concept of oral rehydration therapy advocated by the World Health Organization (WHO).

## BODYMAINTÉ

Year launched 2017

URL http://www.otsuka.co.ip/en/product/bdm/

A conditioning food to support athletic performance that contains BCAA + Arginine and whey protein, in addition to the lactic bacteria B240,\*3 a strain licensed to Otsuka Pharmaceutical. This product is the result of research into the digestive tract and nutrition carried out at the Otsuka Pharmaceutical Otsu Nutraceuticals Research Institute and research into exercise and nutrition carried out by the Otsuka Pharmaceutical Saga Nutraceuticals Research Institute.



Source: GlobalData plo

Sports drinks Juice

Tea drink Coffee Energy drinks

Wate

137,469

## **Functional Foods and Nutritional Supplements**

In the functional foods and nutritional supplements business, the group is accelerating its global expansion through focused investments in organic/gluten-free products in Europe and the supplements business in the U.S.



#### Year launched 1983

Calorie Mate

A product that created a new market for balanced nutritional foods containing all five major nutrients. In 2016, three types of jellies were launched, tailored to hobbies and settings.



## SOYJOY

#### Year launched 2006

A new type of nutrition bar made using only soybean dough (gluten-free) and various other ingredients. In 2016, SOYJOY Crispy was launched as a light, and crunchy bar.



## Gerblé

#### Year launched 2010 (Japan)

A health food from the south of France introduced in 1928 providing nutrients that tend to be lacking in the modern diet from natural ingredients like wheat germ and fruit. The brand is growing with the market expansion of gluten-free products in Europe.

DATA 5

## Other main products



### Nature Made

Year launched 1993 (Japan)

A lineup of nutritional supplements that are free of fragrances, food coloring, or preservatives. First launched in the U.S. in 1972, it is the No. 1 retail vitamin and supplement brand in the U.S.\*

**Oronine H Ointment** 

An ointment for the treatment of skin ailments and

aluminum to laminate, improving convenience.

injuries. In 2015, the tube packaging was changed from

Food with function claims\*2

DATA 6

About Otsuka



### EQUELLE Year launched 2014

A product containing equol, made by fermenting soybeans with Lactobacillus, supporting women's health and beauty. It was the outcome of Otsuka's long years of research on soybeans.

### Kenja-no-shokutaku Double Support

#### Year launched 2005\*3

A product that uses dietary fiber (digestion-resistant dextrin) to slow down the body's absorption of sugars and lipids, thereby reducing the rise in blood glucose levels and triglycerides after a meal

Food for specified health use

The distant	

### InnerSignal Year launched 2005

Second-class OTC drugs

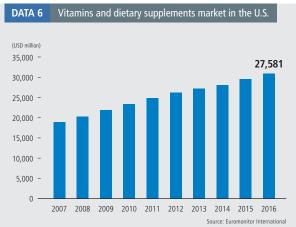
Year launched 1953

A skincare brand for women that employs the active ingredient Energy Signal AMP,\*4 which obtained approval as a quasi-drug with new effects and efficacy for a brighter complexion.



\*1 © 2017, The Nielsen Company, Scantrack® service, US xAOC channels 2007-2016. All rights reserved, no reproduction without permission.
\*3 Launch year of Kenja-no-shokutaku. Kenja-no-shokutaku Double Support was launched in 2012. \*4 Adenosine monophosphate OT \*2 Super Fish Oil, Lutein, Astaxanthin, Fish Oil Pearl, Gingko Biloba





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Creating Corporate Value

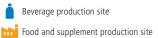




## **Global operations of nutraceutical business**

The nutraceutical business is accelerating its global expansion by promoting growth through brand-building in established markets and expansion into new markets based on the group's regional network.







### FY 2016 FY2016 Business Results





## **Consumer Products Business**

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

## **Overview of business in fiscal 2016**



The group launched *Berry Match* and *Match Set Position* in the *Match* brand of carbonated vitamin drinks. The group worked to energize the brand by continuing with proactive marketing strategies and marketing activities, increasing sales volume over the previous fiscal year. The group focused on marketing activities aimed at expanding the new customer base for mineral water products such as *CRYSTAL GEYSER* and others, but sales volume fell compared to the previous year, due in part to the impact of changes to the revenue structure in the vending machine business. The group refined its product strategy to meet consumer needs and reinforced marketing and sales promotion activities for *Bon Curry*, and despite some impact from competition, continued to improve brand value.

## Fiscal 2017 initiatives

In this business, the Otsuka group endeavored to attract new customers by strengthening its flagship brands such as *Bon Curry* and *Match* and developing new products. In addition, the group refined its marketing strategies and sales promotion activities in order to improve its revenue structure and continued to make reforms to improve cost efficiency.

### **Main products**



```
Year of launch 1968
```

The world's first commercially available food product in a retort pouch



CRYSTAL GEYSER

Year of launch Japan in 1994 Mineral water (soft water)

Mineral water (soft water) bottled directly from spring water sourced at Mount Shasta in California



AVAL

Year of launch 2001 A processed food similar to rice made from konjac

Mannan Hikari



Straight tea with no sugar or flavoring, made with 100% high-quality tea leaves produced on the Indonesian island of Java



### Match

Year of launch 1996

Carbonated vitamin drink

RIDGE

1986 Joined the Otsuka group

Premium wine grown in California; in 2006, earned first place in the 30-year re-enactment of the Judgment of Paris, which was originally held in 1976

### "My Size" series

Based on the concept of a meal that is just the right size, Otsuka Foods launched the 100kcal *My Size* series in 2010. This product, which has moderate calorie content and volume, is offered in a retort pouch that lets customers easily visualize the size of the meal. In 2016, Otsuka Foods launched the *My Size: line! Plus* series, an added-value product, sold exclusively in pharmacies, that promises even more mealtime enjoyment. This line of products targets consumers who are more concerned about their health and watch their salt, protein and carbohydrate intake.



My Size

My Size: line! Plus

## **Other Business**

The Otsuka group operates a broad portfolio of businesses in chemical products, warehousing and distribution, electronic equipment, packaging, and more.

## **Overview of business in fiscal 2016**



In the specialty chemical business, that manufactures and markets functional chemicals, high-performance polymers and materials/compound materials, sales remained level compared with the previous year. In the fine chemical business, that manufactures and markets pharmaceutical intermediates, sales fell compared to the previous year due to a drop in sales prices outside Japan and the impact of exchange rates. In the warehouse and distribution business, the group won more new external customers, and transaction volumes increased due to the promotion of a shared platform (shared logistics) business. Nevertheless overall sales were about the same as the previous year. Revenue in the mail-order support business increased over the previous year due to an increase in the number of transactions.

## Fiscal 2017 initiatives

In the specialty chemical and fine chemical business, the Otsuka group will keep accelerating its drive to enter new markets in and outside Japan. The Otsuka group will also expand its shared platform business and roll out a new logistics system in the warehouse and distribution field.

## Main products and services



## TERRACESS

Friction material for brake pads; magnesium potassium titanate, lithium potassium titanate

## POCone (Medical equipment)

Infrared spectrophotometer that measures the amount of change in the isotope ratio ( $^{13}CI^{12}C$ ) in carbon contained in carbon dioxide in exhaled breath



### Warehouse and distribution

Promotion of joint logistics for group products and other companies' products



## OPTM series

Microscope film thickness meter

## Otsuka Warehouse wins the Logistics Award for the second straight year

Otsuka Warehouse, which is in charge of the group's logistics, won the fiscal 2016 Logistics Grand Prize<sup>\*3</sup> given by the Japan Institute of Logistics Systems for its efforts to reduce long working hours, which is one of the main factors in the lack of truck drivers. This award recognized Otsuka Warehouse's initiatives to address the long working hours of drivers with the proactive use of IT. For example, Otsuka Warehouse reduced waiting time for trucks arriving at the warehouse by using internet reservations for trucks delivering goods; introduced e-receipts, which eliminate inspections when goods enter the warehouse; and devised an efficient delivery system involving the wholesale company that receives the goods.



\*3. Logistics Grand Prize. This award was established with the aim of spreading awareness of logistics and raising awareness of those working in logistics. The award recognizes companies' efforts to advance logistics and their impressive achievements. This award was given for the 33rd time in fiscal 2016. The assessment is carried out based on the six criteria of creativity, scope of outcome, management innovation, technological innovation, social value, and extent of effort.



## **Corporate Governance**

## 1. Basic Approach

The Otsuka group of companies is committed to pursuing steady growth in 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 adheres to the 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.

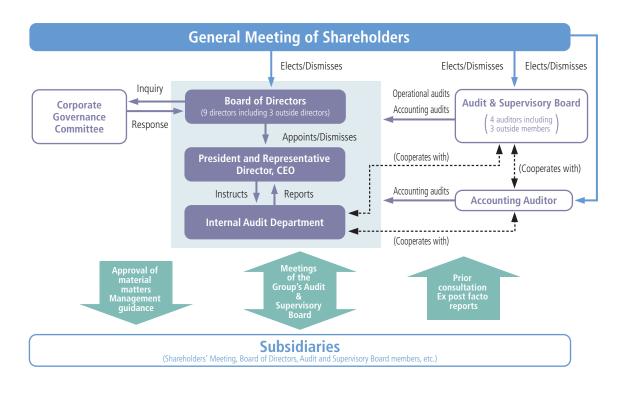
Corporate Governance Guidelines available at the Otsuka Holdings website https://www.otsuka.com/en/company/governance/pdf/guideline.pdf

## 2. Governance System

At Otsuka, the Board of Directors, which includes outside directors, supervises the execution of management plans to ensure sustainable growth and raise corporate value over the medium- to long-term, and fulfills its roles and responsibilities regarding improving profitability and capital efficiency. At Otsuka Holdings, a company with an Audit & Supervisory Board, the Audit & Supervisory Board members, who are independent of the Board of Directors, take the lead in monitoring the execution of operations by the Board of Directors, while coordinating with accounting auditors and the Internal Audit Department. This ensures the Company's health and maintains a solid corporate governance system that can deserve society's trust.

#### Quick Reference (as of March 31, 2017)

Form of organization	Company with an Audit & Supervisory Board
Board of Directors	Nine
of which outside directors	Three (independent directors)
Term of directors	One year
Audit & Supervisory Board members	Four
of which outside Audit & Supervisory Board members	Three (independent directors)
Accounting auditors	Deloitte Touche Tohmatsu LLC



### **Initiatives to Strengthen Corporate Governance**

2008	•Establishment of Otsuka Holdings Co., Ltd. •Term of directors set at one year •Decision not to adopt a directors' retirement benefits system •Corporate officer system adopted •Two outside Audit & Supervisory Board members
2010	•Three outside Audit & Supervisory Board members •Stock options as performance-linked remuneration introduced •Stock publicly listed in December
2011	•First Medium-Term Management Plan announced
2013	•Two outside directors, three outside Audit & Supervisory Board members
2014	•Second Medium-Term Management Plan announced •Three outside directors, two outside Audit & Supervisory Board members •Otsuka Group Global Code of Business Ethics established
2015	•Corporate Governance Guidelines established •Whistleblowing System established externally (Otsuka Holdings and major group companies)
2016	•Three outside directors, three outside Audit & Supervisory Board members •Effectiveness of Board of Directors evaluated •Stock options conditional on progess with the medium-term management plan introduced
2017	•Corporate Governance Guidelines revised •Corporate Governance Committee established •Effectiveness of Board of Directors evaluated based on questionnaire completed by all directors and Audit & Supervisory Board members

### a) Corporate Organization

As a company with an Audit & Supervisory Board, Otsuka Holdings has a Board of Directors and an Audit & Supervisory Board and also engages an independent accounting auditor. The Articles of Incorporation specify that the number of directors shall not exceed eighteen. The Articles of Incorporation also specify that the number of Audit & Supervisory Board members shall not exceed five.

### b) 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.

### c) Corporate Governance Committee

Otsuka Holdings established a Corporate Governance Committee in February 2017. As an advisory council to the Board of Directors, the Committee discusses the nomination of directors and Audit & Supervisory Board members, director remuneration structure and levels, and other corporate governance issues, and then reports to the Board of Directors. The Committee consists of the president, the director who is in charge of administration, and the outside directors. The president serves as chair of the Committee.

## d) Audit & Supervisory Board Members and the Audit & Supervisory Board

The Audit & Supervisory Board members attend and express opinions at meetings of the Board of Directors and monitor the legality and soundness of management as shown in the directors' performance of their duties. Audits by the Audit & Supervisory Board are at the core of this process. Striving to improve audit effectiveness, the Audit & Supervisory Board members also 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.

### e) Evaluation of Effectiveness of the Board of Directors

The effectiveness of the Board of Directors is evaluated based on a questionnaire given to all directors and Audit & Supervisory Board members. The Board of Directors reviews and deliberates on the results of the questionnaire. The questionnaire, prepared by the Board of Directors' secretariat with advice from external organizations, is given to members of both boards in the first two months of each year. The questionnaire results are also reviewed by attorneys.

At a meeting held in March 2017, the Board of Directors discussed its effectiveness and efficacy, including the status of the Board's operations and deliberations, and determined that the Board was functioning adequately. The directors also discussed initiatives to improve quality further. 📋 Corporate Governance

### f) Independent Directors

When selecting outside directors and outside Audit & Supervisory Board members, Otsuka Holdings looks for individuals with broad insight and extensive experience in various fields. The Company requires that candidates have the ability to exercise an adequate management oversight function in respect of the directors through fair and objective monitoring, supervision, and audit of management from a neutral and objective viewpoint. In addition to requiring that outside directors have not been involved in business execution at a group company in the past, Otsuka Holdings has established independence standards for outside directors in order to ensure their independence. These standards are set out in the Company's Corporate Governance Guidelines. They also apply to outside Audit & Supervisory Board members. In addition, the Company registers its outside directors and outside Audit & Supervisory Board members as independent directors with the Tokyo Stock Exchange, since they meet the criteria for independent directors established by the exchange.

### **Rationale for Selection of Outside Directors and Outside Audit & Supervisory Board Members**

Name		Rationale for selection		No. of times attended in FY2016	
				Audit & Supervisory Board meeting	
	Yasuyuki Hirotomi	The Company has determined that, given his abundant experience and extensive knowledge and expertise of corporate management gained through many years in the finance industry, Mr. Hirotomi will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	13/13	_	
Outside director	Tadaaki Kounose	The Company has determined that, given his abundant experience and extensive knowledge and expertise gained through many years in corporate management in the food industry, Mr. Kounose will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	13/13	_	
	Yukio Matsutani	The Company has determined that, given his abundant experience and extensive knowledge and expertise gained in the healthcare and welfare field, Mr. Matsutani will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	9/10	_	
	Norikazu Yahagi	The Company has determined that, given his abundant experience and extensive knowledge as an outside auditor for publicly listed companies over many years, Mr. Yahagi will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	13/13	14/14	
Outside Audit & Supervisory Board members	Hiroshi Sugawara	The Company has determined that, given his specialized knowledge as a certified public accountant, Mr. Sugawara will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	13/13	14/14	
	Yoko Wachi	The Company has determined that, given the far-reaching experience gained in her years as an attorney and her extensive knowledge of the law overall, Ms. Wachi will be able to give effective advice to the Company's managers from a neutral and objective perspective and is suitable as an independent director.	10/10	11/11	

Note: The aforementioned number of Board of Directors meetings and Audit & Supervisory Board meetings attended by outside director Yukio Matsutani and outside Audit & Supervisory Board member Yoko Wachi differ from those of other directors because they were newly appointed at the eighth General Meeting of Shareholders held on March 30, 2016.

### Independence Standards for Outside Directors (Corporate Governance Guideline 8. (3))

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

- 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 had one or more transactions with the Otsuka group, and the amount of such transaction(s) in any fiscal year within the past three fiscal years exceeds 2% of consolidated net sales of either company.
- 3. The outside director, as a legal, accounting or tax expert or as a consultant, has received remuneration exceeding ¥5 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.

### g) Internal Audit Department

The Company's Internal Audit Department 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. These audits consider operations with regard to the assets and overall affairs of the Company and its affiliated companies. The department submits audit reports to the president, directors, and Audit & Supervisory Board members. When a need for improvement is indicated, the department recommends actions to be taken and afterward confirms the status of their implementation in order to optimize the performance of the Company's duties. The department also shares information with Audit & Supervisory Board members and the accounting auditor and in other ways cooperates with them.

### h) Internal Control Department

The Company's Internal Control Department handles 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 which ensures that executives reliably assess internal controls.

The Company's basic approach to internal control and the status of establishment of that system are described in the corporate governance report submitted to the Tokyo Stock Exchange.

#### i) 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.

### j) Status of Accounting Auditor

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 eleven other certified public accountants and four other people. All of the certified public accountants who audited the Company's accounts have done so continuously for less than seven years.

### 3. Director Remuneration

The director remuneration system is designed to ensure that the Company attracts and retains talented leaders and motivates them to deliver superior performance, thereby supporting steady growth in the group's earnings and corporate value.

## a) Amount of Director Remuneration at the Company as a Holding Company

Director remuneration consists of fixed remuneration set depending on position, bonuses linked to performance that provide short-term incentives, and stock options that provide medium- to long-term incentives.

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

	Total	Total remuneration, by type (¥ million)			Number of
Officer category	remuneration etc. (¥ million)	Basic remuneration	Amount charged as cost of stock options	Bonus	officers who receive basic remuneration
Directors ( excluding outside directors	) 497	256	118	121	6
Audit & Supervisory Boar members excluding outside Audit & Supervisor Board members	28	28	_	_	2
Outside director	s 52	52	_	_	7

### 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 essentially paid only basic remuneration; there are no variable components based on earnings.

## Compliance

The Otsuka group has maintained an organization and corporate climate which enable all employees to behave with extremely high ethical standards, including compliance with laws, regulations, and bioethics.

## **Promoting Compliance**

The Otsuka group of companies formulate their own individual programs to promote compliance based on the Otsuka Group Global Code of Business Ethics. The group companies that are involved in the pharmaceutical business follow the JPMA Promotion Code for Prescription Drugs, which is a code of behavior for healthcare professionals, and have formulated their own Code of Practice. The Otsuka group works to forge relationships of mutual trust with medical practitioners, as well as with all of its stakeholders, to foster appropriate collaboration on compliance issues. As the social responsibility to clearly specify the relationship between pharmaceutical companies and healthcare-related organizations is required, it is striving to ensure adherence to standards in order to fulfill its responsibility as a pharmaceutical company and ensure the practice of proper medical care based on ethics and a patient-centered commitment.

## Expanding the Internal Whistleblowing System

Japan's Corporate Governance Code calls for the establishment of a whistleblowing system that is independent of management and for management oversight of the operational status of the system. This independence and oversight is extremely important for a whistleblowing system to function in the quick detection of illegal and inappropriate conduct and/or information disclosure. Accordingly, the Otsuka group has established a whistleblowing system that is independent of management to ensure that whistleblowers can use the system without concerns about potential repercussions.

## Implementing Group-wide Training

- Global Code of Business Ethics and a Global Anti-Corruption Policy -

In order to promote and achieve group-wide compliance under the banner of its corporate philosophy, the Otsuka group established the Otsuka Group Global Code of Business Ethics. The commitment to this Code is publicly posted on its website as a message from the president.

At the same time, the group established the Otsuka Group Global Anti-Corruption Policy which delineates the group's approach to preventing corruption at all of its sites worldwide and promotes its business based on the highest standards of ethical conduct.

To ensure that the same training is implemented at all companies in the Otsuka group, individual group companies are provided with training materials used worldwide on the Global Code of Business Ethics and the Global Anti-Corruption Policy. This compliance training is implemented at least once a year. In addition to Japanese, training materials are also provided in English, Chinese, and Indonesian.

### President's Message Otsuka Group Global Code of Business Ethics

United under the banner of our corporate philosophy, "Otsuka-people creating new products for better health worldwide," we are working tirelessly toward a shared vision: improving global health through innovative products and services. As a "Big Venture Company," we keep moving forward, constantly asking ourselves the following questions: Is our work innovative? Are we meeting the needs of our patients and consumers globally? Do our pharmaceutical products bring something innovative to healthcare? Can our nutraceutical products create new markets?

As we strengthen our presence in the international marketplace, we have a heightened duty to continue fulfilling our ethical and legal obligations as a responsible global corporate citizen. To earn and secure the trust and confidence of our stakeholders including patients and consumers, we operate our business ethically, and with integrity.

The Otsuka Group Global Code of Business Ethics embodies and reiterates our commitment to integrity, which remains steadfast across the Otsuka group worldwide. I strongly hope that our adherence to the principles set forth in this Code promotes a fair and open workplace inspiring creativity, empowering us to reach our fullest potential, and enabling us to enhance the quality of life worldwide.

### Tatsuo Higuchi President and Representative Director, CEO

President and Representative Director, CE Otsuka Holdings Co., Ltd.

## **Risk Management**

In order to fulfill its social responsibilities as a healthcare company, the Otsuka group works to manage risks under normal conditions and prepares to continue operations safely even at times of disaster or emergency.

## **BCP and BCM Establishment**

The Otsuka group has business continuity plans (BCP) in place to ensure that the group continues to operate as effectively as possible and is able to maintain a stable supply of its products, even when large-scale earthquakes and disasters strike.

Otsuka Holdings, the holding company of the group, is certified under ISO 22301 (the international standard for business continuity management systems). This certification verifies that the major operating companies, such as Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, and Otsuka Warehouse, provides a framework capable of ensuring the stable supply of pharmaceuticals, food products, and beverages in both ordinary and emergency conditions. In 2016, major operating companies conducted joint desktop exercises simulating a severe earthquake along the Nankai Trough. Company offices in Tokushima, Tokyo, and Osaka communicated via video conferencing to test the group's collaborative structure for ensuring a stable supply of products under simulated conditions, and results were extremely close to projected scenarios.

As a manufacturer of the intravenous solutions that would be required to administer emergency medical treatment, Otsuka Pharmaceutical Factory has designated business continuity management (BCM) as a key management strategy. The company has enacted basic BCM rules and implements a variety of measures to preempt risk factors and limit damage should an unavoidable crisis occur. The company works for risk management, in cooperation with group companies, for instance by holding regular BCP meetings and establishing a dispersive logistics system.



Otsuka Pharmaceutical Factory: Full-circumference seawall installed at Matsushige Factory

y Otsuka Pharmaceutical Factory: Emergency LED lights along evacuation routes and at evacuation sites automatically turn on during a power outage.

Information Security Initiatives

The Otsuka group has formed the Otsuka Group Information Security Committee for the purpose of sharing the latest information on information security and reviewing specific security measures. Otsuka focuses on boosting the level of comprehensive security throughout the entire group and continuously improving the information security process.

In order to counter the risk of cyber-attack, the Otsuka group enforces a number of measures, such as arranging system security audits by an external expert body, diagnosing website vulnerabilities, conducting drills related to targeted email attacks, and monitoring the content of social media messages. In addition, the group conducts regular emergency drills focusing on systems that are vital to database management.

The Otsuka group has established a privacy protection management system to protect customers' valuable personal information and has acquired PrivacyMark certification and Information Security Management System (ISMS) certification in businesses where this certification is relevant.

Otsuka Pharmaceutical: Comprehensive disaster drill

Each Otsuka group company focuses on in-house training to raise awareness of information security and protection of personal information.



# **Directors, Audit & Supervisory Board Members**



Front row, from left: Sadanobu Tobe, Atsumasa Makise, Ichiro Otsuka, Tatsuo Higuchi, Yoshiro Matsuo, Masayuki Kobayashi Back row, from left: Yukio Matsutani, Tadaaki Kounose, Yasuyuki Hirotomi, Takaharu Imai, Norikazu Yahagi, Hiroshi Sugawara, Yoko Wachi

## Directors

Chairman and Representative Director

## Ichiro Otsuka

April 1987	Joined Otsuka Pharmaceutical Factory, Inc.
June 1997	Executive Director, Director of Consumer Products Development Division, Otsuka Pharmaceutical Co., Ltd.
June 1998	Managing Director, responsible for Consumer Products, Publicity, Promotion and Development Division, Otsuka Pharmaceutical Co., Ltd.
December 2001	Executive Director, Research and Development, Otsuka Pharmaceutical Factory, Inc.
May 2002	Representative Director, Otsuka Pharmaceutical Factory, Inc.
December 2003	Vice President and Representative Director, Otsuka Pharmaceutical Factory, Inc.
December 2004	President and Representative Director, Otsuka Pharmaceutical Factory, Inc.
July 2008	Executive Director, Otsuka Holdings Co., Ltd.
June 2010	Vice President and Executive Director, Otsuka Holdings Co., Ltd.
June 2014	Representative Director, Otsuka Pharmaceutical Factory, Inc. Vice Chairman and Representative Director, Otsuka Holdings Co., Ltd.
March 2015	Executive Director, Otsuka Pharmaceutical Co., Ltd. (Current Position) Chairman, Otsuka Pharmaceutical Factory, Inc. (Current Position) Chairman and Representative Director, Otsuka Holdings Co., Ltd. (Current Position)

### President and Representative Director, CEO

## Tatsuo Higuchi

March 1977	Joined Otsuka Pharmaceutical Co., Ltd.
June 1998	Senior Managing Director, Otsuka Pharmaceutical Co., Ltd. (Pharmavite LLC.)
November 1998	Vice President and Executive Director, Otsuka Pharmaceutical Co., Ltd.
June 1999	Executive Director, responsible for U.S. Business, Otsuka Pharmaceutical Co., Ltd
June 2000	President and Representative Director, Otsuka Pharmaceutical Co., Ltd.
June 2008	Executive Director, Otsuka Pharmaceutical Co., Ltd.
July 2008	President and Representative Director, Otsuka Holdings Co., Ltd. (Current Position)
December 2011	Executive Director, Otsuka Chemical Co., Ltd. (Current Position)
February 2015	President and Representative Director, Otsuka Pharmaceutical Co., Ltd. (Current Position

### Senior Managing Director, Finance

## Atsumasa Makise

December 1987	Joined Otsuka Pharmaceutical Co., Ltd.
June 2002	Operating Officer, Director of ODPI Division, Otsuka Pharmaceutical Co., Ltd.
June 2003	Operating Officer, Director, Finance Department of OIAA Division, Otsuka Pharmaceutical Co., Ltd.
June 2007	Managing Director, Finance and Accounting, Otsuka Pharmaceutical Co., Ltd.
July 2008	Senior Managing Director, Finance, Otsuka Holdings Co., Ltd. (Current Position)
May 2009	Chairman and CEO, Otsuka America Inc.
April 2010	Chairman, Otsuka America Inc.
March 2017	Executive Director, Otsuka Foods Co., Ltd. (Current Position)

## **Yoshiro Matsuo**

April 1985	Joined Otsuka Pharmaceutical Co., Ltd.
January 2003	Operating Officer, Associate General Manager of the General Affairs Department, Otsuka Pharmaceutical Co., Ltd.
June 2006	Operating Officer, General Manager of the General Affairs Department, Otsuka Pharmaceutical Co., Ltd.
November 2007	Senior Operating Officer, General Manager of the General Affairs Department with additional responsibility for Legal Affairs and External Relations, Otsuka Pharmaceutical Co., Ltd.
July 2008	Managing Director, Corporate Administration, Otsuka Holdings Co., Ltd.
March 2016	Senior Managing Director, Administration, Otsuka Holdings Co., Ltd. (Current Position)
January 2017	Executive Director, Otsuka Medical Devices Co., Ltd. (Current Position)

#### **Executive Director**

## Masayuki Kobayashi

October 1993	Joined Taiho Pharmaceutical Co., Ltd.
August 2002	President, Taiho Pharma USA, Inc. (present-day TAIHO ONCOLOGY, INC.)
September 200	Executive Director, Taiho Pharmaceutical Co., Ltd.
April 2010	President and CEO, Otsuka America, Inc.
April 2012	President and Representative Director, Taiho Pharmaceutical Co., Ltd. (Current Position) Executive Director, Taiho Pharma USA, Inc.
April 2014 Mar 2017	Chairman, TAIHO ONCOLOGY, INC. (Current Position) Executive Director, Otsuka Holdings Co., Ltd.(Current Position)

#### **Outside Director**

## Tadaaki Kounose

April 1970	Joined Snow Brand Milk Products Co., Ltd. (present-day MEGMILK SNOW BRAND Co., Ltd.)
June 2002	President and Representative Director, Snow Brand Milk Products Co., Ltd.
October 2009	President and Representative Director, MEGMILK SNOW BRAND Co., Ltd.
April 2011	Director and Advisor, MEGMILK SNOW BRAND Co., Ltd.
June 2011	Special Advisor, MEGMILK SNOW BRAND Co., Ltd.
September 201	1 Administrative Council member, University of Miyazaki, National University Corporation (Current Position)
June 2014	Outside Director, Otsuka Holdings Co., Ltd. (Current Position)

## **Audit & Supervisory Board Members**

### Standing Audit & Supervisory Board Member

## Takaharu Imai

April 1972	Joined TORAY INDUSTRIES, INC.
June 2003	General Manager of International Department, TORAY INDUSTRIES, INC.
July 2005	General Manager of Accounting Department, Otsuka Pharmaceutical Co., Ltd.
April 2006	Operating Officer, General Manager of Accounting Department, Otsuka Pharmaceutical Co., Ltd.
June 2007	Operating Officer, Finance of OIAA Division, Otsuka Pharmaceutical Co., Ltd.
June 2010	Senior Operating Officer, General Manager of OIAA Finance, Accounting Department, Otsuka Pharmaceutical Co., Ltd.
December 2011	Outside Audit & Supervisory Board Member, Otsuka Chemical Co., Ltd.
June 2014	Standing Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)
March 2015	Audit & Supervisory Board Member, Otsuka Chemical Co., Ltd. (Current Position)

### Outside Audit & Supervisory Board Member

## Hiroshi Sugawara

 October 1997
 Joined Chuo Audit Corporation

 October 2000
 Joined Deloitte Touche Tohmatsu (present-day Deloitte Touche Tohmatsu LLC)

 February 2006
 Vice President, Will Capital Management Co., Ltd. (Current Position)

 June 2010
 Outside Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

 June 2012
 Outside Audit & Supervisory Board Member, Otsuka Pharmaceutical Co., Ltd. (Current Position)

 October 2013
 Outside Director, NIPPON PARKING DEVELOPMENT Co., Ltd.

 November 2013
 Standing Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd.

### Executive Director

## Sadanobu Tobe

	Senior Managing Director and Representative Director, Shinko Foods Co., Ltd. (present-day Otsuka Foods Co., Ltd.)
July 1993	Vice President and Representative Director, Otsuka Foods Co., Ltd.
	Vice President and Representative Director, Otsuka Chemical Holdings Co., Ltd. (present-day Otsuka Chemical Co., Ltd.)
May 2006	President and Representative Director, Otsuka Chemical Holdings Co., Ltd.
July 2008	Executive Director, Otsuka Holdings Co., Ltd.
June 2009	Vice Chairman and Representative Director, Otsuka Foods Co., Ltd.
June 2011	Chairman and Representative Director, Otsuka Chemical Co., Ltd.
June 2012	Vice Chairman, Otsuka Foods Co., Ltd.
June 2013	Standing Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd.
November 2013	President and Representative Director, Otsuka Foods Co., Ltd. (Current Position)
June 2014	Executive Director, Otsuka Holdings Co., Ltd. (Current Position)

### **Outside Director**

## Yasuyuki Hirotomi

April 1978	Joined The Daiwa Bank, Ltd. (present-day Resona Bank, Limited)
October 2003	Executive Officer, Resona Bank, Limited
June 2005	Managing Executive Officer, Resona Bank, Limited
April 2008	Senior Executive Officer, Resona Bank, Limited
June 2008	Director and Senior Executive Officer, Resona Bank, Limited
June 2009	Vice President and Representative Director and Executive Officer, Resona Bank, Limited
June 2011	Director, The Kinki Osaka Bank, Ltd.
June 2013	Outside Director, ELECOM CO., LTD. (Current Position)
June 2013	Outside Director, Otsuka Holdings Co., Ltd. (Current Position)
June 2014	Board Director and Senior Vice President, KYOEI STEEL LTD. (Current Position)

### **Outside Director**

## Yukio Matsutani

April 1975	Intern, Pediatric Department, St. Luke's International Hospital
October 1981	Joined Ministry of Health and Welfare (present-day Ministry of Health, Labour and Welfare)
August 2005	Director-General, Health Policy Bureau, Ministry of Health, Labour and Welfare
August 2007	Director, National Sanatorium Tama Zenshoen
April 2012	President, National Institute of Public Health
December 2015	Vice President, International University of Health and Welfare (Current Position)
March 2016	Outside Director, Otsuka Holdings Co., Ltd. (Current Position)

Finance & General Information

#### Outside Audit & Supervisory Board Member

## Norikazu Yahagi

April 1966	Joined IBM Japan Ltd.
March 1999	Statutory Auditor, IBM Japan Ltd.
June 2002	External Audit & Supervisory Board Member, SQUARE CO., LTD. (present-day SQUARE ENIX HOLDINGS CO., LTD.)
October 2002	Executive Director, Japan Audit & Supervisory Board Members Association
June 2004	Outside Audit & Supervisory Board Member, T.D.I. CO., LTD.
July 2008	Outside Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

**Outside Audit & Supervisory Board Member** 

## Yoko Wachi

April 1989	Registered as an attorney at law (Dai-ichi Tokyo Bar Association), Joined KAJITANI LAW OFFICES (Current Position)
June 2015	Corporate Auditor, NICHIAS Corporation (Current Position)
March 2016	Outside Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

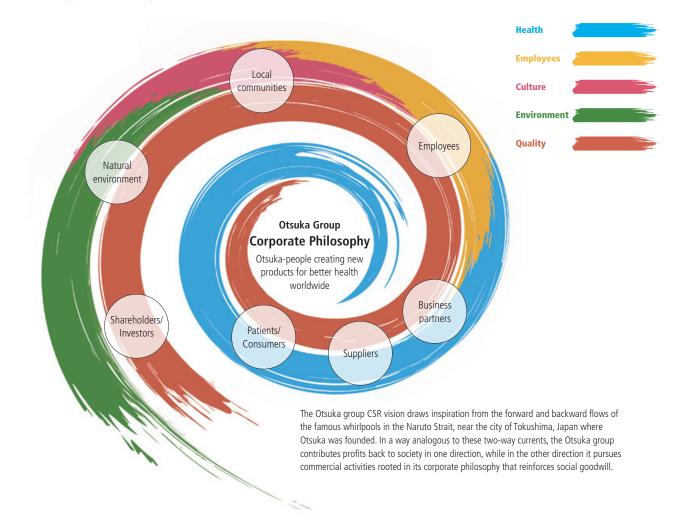
FY2016 Business Results



## **Otsuka Group CSR Vision**

Otsuka's approach to social responsibility is driven by the commitment to live up to its corporate philosophy, "Otsuka-people creating new products for better health worldwide." Otsuka's CSR initiatives evolve as stakeholders become increasingly engaged. This is only natural, since Otsuka's business activities require the understanding, cooperation and support of many stakeholders, including local communities, business partners, patients, and consumers.

Otsuka contributes to society in various ways, including initiatives that benefit the local communities where it operates and that protect the environment. These initiatives directly and indirectly help Otsuka to improve its manufacturing and services. However, delivering products and services valued by customers does more than help develop the group's business. With this approach, Otsuka also creates virtuous cycles of trust, loyalty and support through emphasis on areas such as community partnerships. By pursuing CSR as an integral part of its business, Otsuka will continue as a valued, necessary partner for society.



### Five Areas of Otsuka Group CSR

### Health

As a total healthcare company, the Otsuka group is focused on developing innovative products and seeking ways to maintain and promote better health for all.

### Environment

Our lives, communities and business activities are inextricably linked to the environment. The Otsuka group embraces its responsibility to care for the environment and pursue sustainability at every stage, from the manufacturing of products through to their use.

### Quality

Otsuka's approach to quality extends beyond the safety and security of product manufacturing. Striving to enhance the quality of its social initiatives, the group engages in a broad range of activities, from information transparency and disclosure to collaboration with other businesses, respect for local communities, and ensuring compliance with regulations.

### Culture

Otsuka respects local communities and their time-honored 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.

#### Employees

The spirit of sozosei (creativity) instilled in every employee of the Otsuka group stems from the desire to realize the corporate philosophy. The group fosters a culture that encourages a diverse workforce to break away from convention, broaden their perspectives, and pursue personal development. This collective creativity, in turn, enables the group to continue to develop innovative products that enrich society.

## **Initiatives in the Spotlight**

This section features flagship initiatives for contributing to local communities in the field of "culture," selected from the extensive CSR activities of the Otsuka group. The Otsuka group strives to be a good corporate citizen in all of the communities where it does business. The group cares about the natural environment and the local community, values the local culture, and strives to contribute to society in unique ways that only the Otsuka group can.

For more on the Otsuka group's CSR initiatives, visit the Otsuka group CSR website.

Otsuka Group CSR portal

https://www.otsuka.com/en/csr/hd\_activity/

## **Meeting Local Needs with Medical Contribution Initiatives**

- Otsuka Welfare Clinic: A Free Medical Clinic for Afghan Refugees -

Twenty-three Otsuka group companies that operate in Asia and the Middle East, including Otsuka Pharmaceutical and Otsuka Pakistan Ltd., founded the Otsuka Welfare Clinic, a medical clinic for Afghan refugees, in Peshawar, Pakistan, in 2003. The clinic has provided free medical service for almost 15 years.

Since 2001, approximately 1.8 million refugees have fled to Pakistan from neighboring Afghanistan. Refugee camps, which are desperately short of food and clothing, have required international aid. Many international agencies, NPOs, NGO groups, corporations and others have provided material and funding relief. Otsuka Pakistan, which manufactures and sells intravenous solutions locally, has also provided intravenous solutions through the Red Cross as relief supplies. Witnessing the inadequate access to medical treatment in the refugee camps, and with a strong desire to contribute to the health of local people and provide aid to people suffering from illness directly, the Otsuka group, as a healthcare company which operates in Asia and the Middle East, carried out a wide-ranging series of studies and decided to establish a medical clinic to make assistance suited to local conditions more accessible.

As of 2017, the clinic employs eight regular staff, including three physicians, assisted by nurses, pharmacists, and midwives. The clinic provides treatment for respiratory, digestive, dermatological, obstetric, and gynecological ailments as well as ophthalmology and otolaryngology. The local culture and religion are taken into account in the operation of the medical clinic, including a resident female physician in consideration of female patients.

When it first opened, the medical clinic was not well known, and only seven patients visited on the first day. To remedy this situation, nearby refugee camps were visited to start communicating about the clinic, which now sees about 160 patients a day and has treated a total of more than 880,000 people. The clinic sees not only Afghan refugees from the camps but nearby residents as well. In addition, at the time of the Pakistan earthquake in 2005 and the heavy flooding caused by severe rainfall in the region in 2010, clinic staff traveled to the severely affected areas to set up temporary treatment facilities to provide care.

In recognition of these local, ongoing medical contribution activities, eight years after its foundation, the Otsuka Welfare Clinic was awarded a certificate of commendation in 2011 by Japan's ambassador to Pakistan for its outstanding contribution to community welfare through the ongoing provision of free medical care to many patients, and for its significant contribution to deepening friendly ties between Japan and Pakistan. Furthermore, in 2014, Otsuka Pharmaceutical was awarded a commendation from the Japanese Minister of Foreign Affairs, a recognition given to individuals and groups for their achievements in promoting friendly ties between Japan and other countries. This award recognized the contributions made over more than a decade to Afghan refugees in Pakistan and to the promotion of local medical care.

Going forward, the Otsuka group will continue to make locally based medical contributions that contribute to people's health, based on its corporate philosophy, "Otsuka-people creating new products for better health worldwide."



### **Overview of Otsuka Welfare Clinic**

Established: Address:

Activities:

- June 16, 2003 (Opened in July) Bungalow NO 239-Khalil Town Danish Abad Road, Opposite Railway Line Taxi Stand-Board Bazar, Peshawar, Pakistan
- Free medical treatment for Afghan refugees and nearby residents
   Providing not only Otsuka drugs, but also other companies' drugs in conjunction with necessary treatment
- Ensuring a resident female physician in consideration of the local religion and culture
- Consultations with physicians in the languages of both Afghanistan and Pakistan
- Running activities tailored to local needs, including establishment of temporary treatment facilities in areas severely affected by disasters such as earthquakes and flooding

# **Corporate Social Responsibility**

## **Coexisting with Communities in Indonesia**

— SATU HATI (One Heart) Programs —

The Otsuka group established its first Indonesian company, P.T. Otsuka Indonesia, in 1974, launching the intravenous solutions business. Subsequently, business expanded into pharmaceuticals and nutritional products, and today there are six Otsuka group companies in Indonesia operating in both the pharmaceutical and nutraceutical businesses.

P.T. Amerta Indah Otsuka, which manufactures and sells POCARI SWEAT, implements social contribution activities based on the three main themes of "SATU HATI Cerdaskan Bangsa One Heart: Education for All



Children," "SATU HATI Peduli Lingkungan One Heart: Consideration for the Whole Environment," and "SATU HATI Sehatkan Bangsa One Heart: Health for Every Citizen."

## **Providing Learning Centers for the Children Who Will Shape the Future**

The 2006 Central Java Earthquake caused severe damage, including the destruction of many school buildings. In order to help with the reconstruction of these damaged schools, in addition to making donations, P.T. Amerta Indah Otsuka held a charity concert, calling on the wider society to cooperate in its assistance activities. This initiative has had the support of the media and the Indonesian government since 2007, growing into a charity program entitled SATU HATI Cerdaskan Bangsa One Heart: Education for All Children" and launching a new fund raising campaign. The funds raised were presented to elementary schools all around Indonesia in the form



SATU HATI charity concert



Library built in 2011

Children reading books in the library

of books. In 2008, even more donations were collected, enabling the construction of elementary school libraries. Since then, the SATU HATI program has enlisted the support of local non-profit organizations and the Indonesian Ministry of Women Empowerment and Child Protection. As a result of all of these support activities, 28 libraries have been built and more than 124,000 books donated since 2007.

This program, which is focused on contributing to education for children, also extends beyond the donation of libraries and books. At the Kejayan Plant production site for POCARI SWEAT in East Java, a community learning center has been set up, and a SATU HATI School (village school) is held once a week. Employees take turns providing after-school tutoring in science and math for elementary school students. The plant has adopted the concept of "open space and interaction with the local community" and has opened up its site, allowing it to be used for recreational



SATU HATI School held at Kejayan Plant

Children studying at SATU HATI School

activities such as soccer. Nearby residents are also welcomed to the mosque for Friday prayers and Ramadan, contributing to community-building.

## **Community-Oriented Environmental Protection Activities**

In addition to supporting children's education, the SATU HATI initiative has also grown to include assistance and education designed to raise environmental awareness and contribute to health.

As one of the programs under "SATU HATI Peduli Lingkungan One Heart: Consideration for the Whole Environment," P.T. Amerta Indah Otsuka cooperates with NGOs and local residents to implement environmental conservation activities in the POCARI SWEAT water catchment area. In February 2016, 12,500 pine trees were planted on Mount Bromo. The slopes of Mount Bromo form the catchment for Pasuruan, where the Kejayan POCARI SWEAT Plant is located. The planting was carried out to protect the water resources of Pasuruan and the environment of the Mount Bromo area, together with local government and environmental groups and with the approval and support of the Pasuruan government. Approximately 50 Otsuka employees participated in the planting activity in 2016.



Employees planting trees on the nearby mountain to protect the water sources around the plant

## **Health Promotion Activities**

Furthermore, as one of the programs under "SATU HATI *Sehatkan Bangsa* One Heart: Health for Every Citizen," the Otsuka group implements activities for the reduction of garbage, including environmental education to give residents near plants a chance to learn about the importance of collecting street garbage and separating garbage. Improving the sanitary environment supports people's health. Littering and the impact that it has on the environment is a serious social issue in Indonesia. P.T. Amerta Indah Otsuka initiated a project in 2016 to solve this issue, and 300 families attended environmental education in 2016.

The Company also provides support for the operation of clinics for mothers and children. These are held once a month close to the Sukabumi Plant and the Kejayan Plant, which produce *POCARI SWEAT*. At the clinics, volunteer staff who work at local health centers provide basic care for infants and mothers.

Indonesia is the world's largest island nation, and consists of more than 13,000 islands. Its more than 250 million people made up of about 300 ethnicities live together while fostering and passing down diverse ethnic cultures. The Otsuka group respects the diverse cultures rooted in the country and will continue its activities in order to play a role in the development of Indonesia through community interaction and cooperation.

### **SATU HATI Project Initiatives**

## Cerdaskan Bangsa

(education support activities)

- Construction of libraries
- Donation of books
- Establishment and operation of community education centers SATU HATI School (village classroom)

### Peduli Lingkungan

(environmental conservation activities)

- Tree planting and afforestation
- Coastal cleanup activities
- Urban forest regeneration activities

### Sehatkan Bangsa

(health promotion activities)

- Support for operation of clinics for mothers and children
- Garbage reduction activities in collaboration with Indonesia's Ministry of Health



With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.

				J-GAAP		
	Item*1		2009.3	2010.3	2011.3	
Results of Operations	Net sales		¥ 955.9	¥1,084.3	¥1,127.6	
	Selling, general and administrative expenses*	2	405.9	477.4	457.6	
	Research and development expenses		135.9	151.8	164.7	
	R&D ratio	(%)	14.2	14.0	14.6	
	Operating profit		91.5	98.5	126.3	
	Operating profit margin	(%)	9.6	9.1	11.2	
	Profit attributable to owners the Company		47.1	67.4	82.4	
Financial Position	Total assets		¥1,298.8	¥1,458.4	¥1,589.7	
	Total equity		863.8	948.5	1,163.3	
	Ratio of equity attributable to owners of the Company to total assets	(%)	62.3	64.2	72.4	
	ROE	(%)	7.2	7.7	7.9	
Cash Flows	Net cash flows from operating activities		¥ 58.5	¥ 173.5	¥ 87.7	
	Net cash flows from (used in) investing activities		(213.6)	(59.0)	(131.5)	
	Free cash flows		(155.1)	114.5	(43.8)	
Dividends*5	Annual dividend per share		¥ 250	¥ 12.5	¥ 28	
	Dividend pay-out ratio	(%)	9.2	8.7	17.0	
Common Stock/ Stock Price*5	Number of shares outstanding at year-end	(1,000) (shares)	23,519	519,157	557,836	
	Stock price at year-end		—	—	¥ 2,055	
Number of Employees**	<sup>3</sup> Total	(persons)	22,928	24,589	25,188	
	Japan	(persons)	13,657	14,174	14,030	
	Overseas	(persons)	9,271	10,415	11,158	

\*1 Item names according to IFRS. Names in J-GAAP correspond to names in IFRS as follows: •Net income/Profit attributable to owners of the Company •Net assets/Equity

\*2 SG&A expense under J-GAAP is presented as total expense less R&D expenses. The Company believes that this is useful to investors in comparing the Company's financial results under J-GAAP with those of IFRS.

\*3 Due to a change in the consolidated fiscal year, fiscal 2014 (ended December 31, 2014) was a transitional period covering the nine months from April 1 to December 31, 2014.

\*4 The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader's convenience, at the rate of 116.49=US\$1, the approximate exchange rate on December 31, 2016.

\*5 The Company conducted a stock split of common stock at a ratio of 20 for 1 with an effective date of June, 2009.

 $^{*}\mathrm{6}$  Number of employees at Otsuka Holdings and its subsidiaries.

Millions of U.S. Dollars*						Billions of Yen
IFRS	RS	IFF		AP	J-GA	
2016.12	2016.12	2015.12	2014.12*3	2014.3	2013.3	2012.3
\$10,263	¥ <b>1,195.5</b>	¥1,427.4	¥1,224.3	¥1,452.8	¥1,218.1	¥1,154.6
4,600	535.9	636.4	508.6	563.4	462.2	457.4
1,449	168.8	202.7	172.9	249.0	192.4	159.2
_	14.1	14.2	14.1	17.1	15.8	13.8
868	101.1	148.9	196.5	198.7	169.7	148.7
_	8.5	10.4	16.1	13.7	13.9	12.9
795	92.6	102.0	143.1	151.0	122.4	92.2
\$21,275	¥ <b>2,478.3</b>	¥2,575.3	¥2,178.2	¥2,028.4	¥1,779.2	¥1,666.8
14,924	1,738.4	1,727.4	1,658.6	1,510.8	1,325.1	1,222.8
_	69.0	66.0	74.7	73.2	73.7	72.5
_	5.4	6.1	9.2	10.8	9.7	7.8
\$ 1,219	¥ <b>142.0</b>	¥ 257.9	¥ 88.5	¥ 226.5	¥ 119.3	¥ 147.6
(1,160)	(135.1)	(422.6)	(28.7)	(108.5)	(91.2)	(107.6)
59	6.9	(164.7)	59.9	117.9	28.1	40.0
U.S. Dollars* <sup>4</sup>						Yen
\$ 0.86	¥ 100	¥ 100	¥ 75	¥ 65	¥ 58	¥ 45
_	58.5	53.1	28.4	23.4	26.1	27.2
_	557,836	557,836	557,836	557,836	557,836	557,836
\$ 43.72	¥ <b>5,093</b>	¥ 4,317	¥ 3,617	¥ 3,087	¥ 3,300	¥ 2,450
_	31,787	31,940	29,482	28,288	25,330	24,595
_	13,909	14,082	14,285	14,116	13,732	13,808
_	17,878	17,858	15,197	14,172	11,598	10,787

**Consolidated Financial Statements** 

Otsuka Holdings and its Subsidiaries as of December 31, 2016

With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.

### **Consolidated Statement of Financial Position**

Consolidated Statement of Fin	ancial Position	Billions of Yen		Millions of U.S. Dollars*		
Assets	IFRS Transition Date (January 1, 2015)	2015.12	2016.12	2016.12		
urrent assets						
Cash and cash equivalents	¥ 459.1	¥ 460.6	¥ 369.9	\$ 3,175		
Trade and other receivables	412.3	387.8	353.2	3,032		
Inventories	143.3	135.8	133.8	1,148		
Income taxes receivable	17.8	2.6	14.4	123		
Other financial assets	137.7	109.0	209.3	1,797		
Other current assets	36.2	44.7	33.0	284		
Subtotal	1,206.4	1,140.6	1,113.5	9,559		
Assets held for sale	_	_	0.3	3		
Total current assets	1,206.4	1,140.6	1,113.9	9,562		
Non-current assets						
Property, plant and equipment	350.5	359.6	358.8	3,080		
Goodwill	92.3	244.7	231.8	1,990		
Intangible assets	206.6	481.2	447.0	3,837		
Investments in associates	183.0	175.8	166.6	1,430		
Other financial assets	154.1	155.6	143.3	1,230		
Deferred tax assets	39.7	9.6	6.9	60		
Other non-current assets	6.1	8.2	10.0	86		
Total non-current assets	1,032.2	1,434.7	1,364.4	11,713		
Total assets	¥2,238.7	¥2,575.3	¥2,478.3	\$21,275		

\* The U.S. dollar amounts in this report represent translations of Japanese yen, solely for the reader's convenience, at the rate of 116.49=US\$1, the approximate exchange rate on December 31, 2016. •For consolidated financial statements and notes to consolidated financial statements, refer to the "Consolidated Financial Statements":

https://www.otsuka.com/en/ir/library/report.html

	Billions of Yen						
Liabilities and equity	IFRS Transition Date (January 1, 2015)	2015.12	2016.12	2016.12			
iabilities							
Current liabilities							
Trade and other payables	¥ 234.0	¥ 150.1	¥ 162.3	\$ 1,394			
Bonds and borrowings	72.1	80.5	79.3	680			
Other financial liabilities	2.3	2.8	3.9	33			
Income taxes payable	14.0	19.0	21.5	184			
Provisions	—	2.1	0.6	5			
Other current liabilities	130.2	225.6	169.1	1,452			
Total current liabilities	452.6	480.0	436.6	3,748			
Non-current liabilities							
Bonds and borrowings	22.7	234.3	194.0	1,665			
Other financial liabilities	16.6	9.1	11.9	103			
Net defined benefit liabilities	38.2	31.2	15.3	132			
Provisions	0.5	0.5	0.5	4			
Deferred tax liabilities	13.0	83.5	70.3	603			
Other non-current liabilities	9.4	9.4	11.2	96			
Total non-current liabilities	100.4	367.9	303.2	2,603			
Total liabilities	553.0	847.9	739.8	6,351			
quity Equity attributable to owners of the Company							
Share capital	81.7	81.7	81.7	701			
Capital surplus	502.9	5,03.4	504.0	4,326			
Treasury shares	(47.4)	(47.3)	(47.3)	(406)			
Retained earnings	1,105.7	1,159.5	1,209.1	10,380			
Other components of equity	10.1	1.1	(37.0)	(318)			
Total equity attributable to owners of the Company	1,653.0	1,698.5	1,710.5	14,684			
Non-controlling interests	32.7	28.9	27.9	240			
Total equity	1,685.7	1,727.4	1,738.4	14,924			
otal liabilities and equity	¥2,238.7	¥2,575.3	¥2,478.3	\$21,275			

With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.

### **Consolidated Statement of Income**

Consolidated Statement of Income	Billion	Millions of U.S. Dollars*		
-	2015.12	2016.12	2016.12	
Net sales	¥1,427.4	¥1,195.5	\$10,263	
Cost of sales	(452.5)	(406.3)	(3,488)	
Gross profit	974.9	789.2	6,775	
Selling, general and administrative expenses	(636.4)	(535.9)	(4,600)	
Research and development expenses	(202.7)	(168.8)	(1,449)	
Share of profit of associates	12.4	16.0	137	
Other income	5.3	4.6	39	
Other expenses	(4.6)	(3.9)	(34)	
Operating profit	148.9	101.1	868	
Finance income	10.0	3.8	33	
Finance costs	(7.8)	(13.1)	(113)	
Other non-operating income (expenses)	(0.7)	24.8	213	
Profit before taxes	150.3	116.7	1,002	
Income tax expenses	(50.9)	(23.3)	(200)	
Profit for the year	¥ 99.4	¥ 93.3	\$ 801	
Attributable to:				
Owners of the Company	102.0	92.6	795	
Non-controlling interests	(2.6)	0.8	7	
arnings per share:		¥	U.S. Dollars	
Basic earnings per share (Yen)	¥188.16	¥170.82	\$1.47	
Diluted earnings per share (Yen)	188.15	170.70	1.47	

### **Consolidated Statement of Comprehensive Income**

Consolidated Statement of Comprehensive Inc	ome Billion	ns of Yen	Millions of U.S. Dollars*		
	2015.12	2016.12	2016.12		
Profit for the year	¥99.4	¥93.3	\$ 801		
Other comprehensive income					
Components that will not be reclassified to profit or loss					
Remeasurements of defined benefit plans	0.6	11.3	97		
Financial assets measured at fair value through other comprehensive income	13.6	(0.9)	(7)		
Share of other comprehensive income of associates	0.2	(0.3)	(2)		
Subtotal	14.3	10.2	88		
Components that may be reclassified to profit or loss					
Foreign currency translation reserve	(12.1)	(29.6)	(254)		
Cash flow hedges	(0.3)	(0.1)	(1)		
Share of other comprehensive income of associates	(11.5)	(9.2)	(79)		
Subtotal	(23.8)	(38.9)	(334)		
Total other comprehensive income	(9.5)	(28.7)	(246)		
Comprehensive income	¥89.9	¥64.6	\$ 555		
Attributable to:					
Owners of the Company	93.6	65.7	564		
Non-controlling interests	(3.8)	(1.0)	(9)		
Comprehensive income	¥89.9	¥64.6	\$ 555		

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## **Consolidated Statement of Changes in Equity**

						Billions	of Yen					
-				Equity at	tributable to	owners of the	Company					
-						Other c	omponents of	equity				
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasure- ments of defined benefit plans	Financial assets measured at fair value through other comprehen- sive income	Foreign currency translation reserve	Cash flow hedges	Total	Total	Non- controlling interests	Total equity
Balance as of January 1, 2015	¥ 81.7	¥ 502.9	¥ (47.4)	¥ 1,105.7	¥ –	¥ 9.7	¥ –	¥ 0.4	¥ 10.1	¥ 1,653.0	¥ 32.7	¥ 1,685.7
Profit for the year	-	-	-	102.0	-	-	-	-	-	102.0	(2.6)	99.4
Other comprehensive income	_	-	-	-	0.6	13.5	(22.1)	(0.3)	(8.3)	(8.3)	(1.2)	9.5
Comprehensive income	_	-	_	102.0	0.6	13.5	(22.1)	(0.3)	(8.3)	93.6	(3.8)	89.9
Purchase of treasury shares	-	-	(0)	-	-	-	-	-	-	(0)	-	(0)
Disposals of treasury shares	-	(0)	0.2	-	-	-	-	-	-	0.1	-	0.1
Dividends	-	_	_	(48.8)	-	-	_	_	-	(48.8)	(0.5)	(49.2)
Changes in ownership interests in subsidiaries that do not result in loss of control	-	0.5	-	-	-	-	-	-	-	0.5	0.5	1.0
Transfer from other components of equity to retained earnings	-	-	-	0.6	(0.6)	(0.1)	-	-	(0.6)	-	-	-
Other	-	-	-	0	-	-	-	-	-	0	-	0
Total transactions with owners, etc.	_	0.4	0.2	(48.1)	(0.6)	(0.1)	-	-	(0.6)	(48.2)	0.0	(48.1)
Balance as of December 31, 2015	¥81.7	¥503.4	¥(47.3)	¥1,159.5	¥ –	¥23.1	¥(22.1)	¥ 0.1	¥ 1.1	¥1,698.5	¥28.9	¥1,727.4
Profit for the year	_	-	-	92.6	-	-	-	-	-	92.6	0.8	93.3
Other comprehensive income	_	-	-	-	11.2	(0.7)	(37.3)	(0.1)	(26.9)	(26.9)	(1.8)	(28.7)
Comprehensive income	_	-	_	92.6	11.2	(0.7)	(37.3)	(0.1)	(26.9)	65.7	(1.0)	64.6
Purchase of treasury shares	_	-	(0)	-	-	-	_	-	-	(0)	_	(0)
Dividends	-	-	-	(54.2)	-	-	-	-	-	(54.2)	(0.5)	(54.7)
Share-based payment transactions	_	0.1	-	-	-	-	-	-	-	0.1	_	0.1
Changes in ownership interests in subsidiaries that do not result in loss of control	_	0.4	-	-	_	-	-	_	_	0.4	0.5	1.0
Transfer from other components of equity to retained earnings	-	-	-	11.2	(11.2)	(0.1)	-	-	(11.2)	-	-	-
Total transactions with owners, etc.	-	0.6	(0)	(43.0)	(11.2)	(0.1)	_	-	(11.2)	(53.6)	0	(53.6)
Balance as of December 31, 2016	¥81.7	¥504.0	¥(47.3)	¥1,209.1	¥ –	¥22.4	¥(59.4)	¥ 0	¥(37.0)	¥1,710.5	¥27.9	¥1,738.4

						Millions of L	J.S. Dollars*					
-	Equity attributable to owners of the Company								_			
-	Other components of equity											
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasure- ments of defined benefit plans	Financial assets measured at fair value through other comprehen- sive income	Foreign currency translation reserve	Cash flow hedges	Total	Total	Non- controlling interests	Total equity
Balance as of January 1, 2016	\$ 701	\$ 4,321	\$ (406)	\$ 9,954	\$ -	\$ 198	\$ (190)	\$ 1	\$ 10	\$ 14,580	\$ 248	\$ 14,828
Profit for the year	_	-	-	795	-	-	-	-	-	795	7	801
Other comprehensive income	-	-	-	-	96	(6)	(320)	(1)	(231)	(231)	(15)	(246)
Comprehensive income	_	-	_	795	96	(6)	(320)	(1)	(231)	564	(9)	555
Purchase of treasury shares	-	-	(0)	-	-	-	-	-	-	(0)	-	(0)
Dividends	-	-	-	(465)	-	-	-	-	-	(465)	(4)	(469)
Share-based payment transactions	-	1	-	-	-	-	-	-	-	1	-	1
Changes in ownership interests in subsidiaries that do not result in loss of control	_	4	-	-	-	-	-	_	-	4	5	8
Transfer from other components of equity to retained earnings	_	_	-	96	(96)	(1)	_	_	(96)	-	-	-
Total transactions with owners, etc.	-	5	(0)	(369)	(96)	(1)	-	-	(96)	(460)	0	(460)
Balance as of December 31, 2016	\$701	\$4,326	\$(406)	\$10,380	\$ -	\$192	\$(510)	\$ 0	\$(318)	\$14,684	\$240	\$14,924

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•For consolidated financial statements and notes to consolidated financial statements, refer to the "Consolidated Financial Statements":

https://www.otsuka.com/en/ir/library/report.html

About Otsuka

FY2016 Business Results

Creating Corporate Value

Finance & General Information

# **Consolidated Financial Statements**

With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted the International Financial Reporting Standards (IFRS), on which the present disclosure information is based. Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.

### **Consolidated Statement of Cash Flows**

Consolidated Statement of Cash Flows	Billio	Millions of U.S. Dollars*	
	2015.12	2016.12	2016.12
Cash flows from operating activities			
Profit before taxes	¥150.3	¥116.7	\$1,002
Depreciation and amortization expenses	59.2	59.6	511
Impairment loss and reversal of impairment loss	22.1	32.1	276
Share of loss (profit) of associates	(12.4)	(16.0)	(137)
Finance income	(10.0)	(3.8)	(33)
Finance costs	7.8	13.1	113
Other non-operating expenses (income)	0.7	(24.8)	(213)
Decrease (increase) in inventories	12.8	(0.6)	(5)
Decrease (increase) in trade and other receivables	26.9	22.8	196
Increase (decrease) in trade and other payables	(62.8)	11.6	100
Other	76.3	(30.4)	(261)
Subtotal	271.0	180.3	1,547
Interest and dividends received	8.9	9.2	79
Interest paid	(3.9)	(3.5)	(30)
Income taxes paid	(18.2)	(43.9)	(377)
Net cash flows from (used in) operating activities	257.9	142.0	1,219
Cash flows from investing activities			
Proceeds from sales of property, plant and equipment	1.7	1.7	15
Payments for acquisition of property, plant and equipment	(56.9)	(44.4)	(381)
Payments for acquisition of intangible assets	(18.6)	(27.2)	(234)
Proceeds from sales and redemption of investments	47.5	100.1	859
Payments for acquisition of investments	(51.2)	(72.1)	(619)
Payments for acquisition of subsidiaries	(392.4)	_	_
Decrease (increase) in time deposits	29.6	(111.1)	(954)
Other	17.8	17.9	154
Net cash flows from (used in) investing activities	(422.6)	(135.1)	(1,160)
Cash flows from financing activities			
Purchase of treasury shares	(0)	(0)	(0)
Increase (decrease) in current borrowings	(16.4)	(2.6)	(23)
Proceeds from non-current borrowings	266.7	1.9	17
Repayments of non-current borrowings	(24.5)	(35.8)	(308)
Dividends paid	(49.2)	(54.7)	(470)
Other	(49.2)	(1.8)	(470)
Net cash flows from (used in) financing activities	175.0	(93.1)	(799)
net cash nows nom (asea in) manenty activities	173.0	(55.1)	(799)
ncrease (decrease) in cash and cash equivalents	103	(86.2)	(740)
Cash and cash equivalents at beginning of period	459.1	460.6	3,954
Effect of exchange rate changes on cash and cash equivalents	(8.8)	(4.6)	(39)
Cash and cash equivalents at end of period	¥460.6	¥369.9	\$3,175

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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, 2016)





Established in 1964, Otsuka Pharmaceutical is a total healthcare company. In keeping with its corporate philosophy of "Otsuka-people creating new products for better health worldwide," it aims to treat illness and sustain day-to-day well-being. With a pharmaceutical business that provides breakthrough treatments for patients around the world, and a nutraceutical business that helps healthy people get even healthier, Otsuka Pharmaceutical is engaged in the research, development, manufacturing, and marketing of unique, innovative products.



Founded in 1961, Otsuka Warehouse has been performing consistent logistics for pharmaceuticals and food products ever since. It has built a common distribution platform for the Otsuka group in the three product areas of pharmaceuticals, food and beverages, and daily necessities. In recent years, the company has grown to offer logistics services outside the group.



Otsuka Pharmaceutical Factory was first founded as Otsuka Seiyaku Kogyobu (Otsuka Pharmaceutical) in 1921 and is the original company from which the Otsuka group has grown. The company develops intravenous solutions, along with medical foods such as oral rehydration solutions and many other innovative products to meet a wide range of needs. It also performs contract manufacturing utilizing the technologies it has developed. At present it is expanding the business operations from Japan to the international market focusing in Asia. Otsuka Pharmaceutical Factory delivers safe, high-quality products to patients and healthcare professionals.



Founded in 1950, Otsuka Chemical aims to improve the lives and health of people as well as the environment through its business activities. It offers products and materials that meet a wide range of needs in society. As a manufacturer that develops original technologies, Otsuka Chemical supports customers and aims to continue to grow as a trusted company that provides value for society.

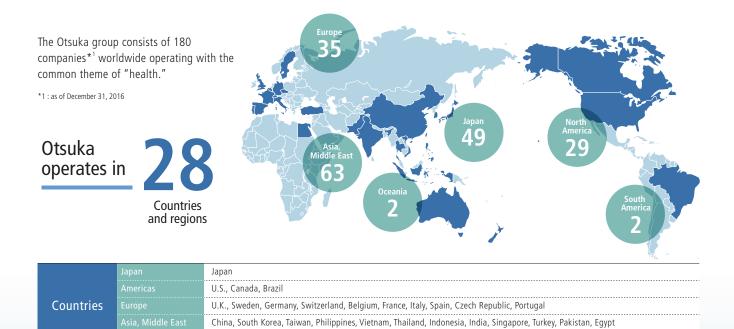


Established in 1963, Taiho Pharmaceutical aspires to be an agile specialty pharmaceutical company trusted the world over, true to its corporate philosophy, "We strive to improve human health and contribute to a society enriched by smiles." It is also taking on the challenge of developing unique pharmaceuticals that can contribute to society. Even in its consumer healthcare business, Taiho Pharmaceutical strives to create and develop a unique brand that consumers will be loyal to for years to come.



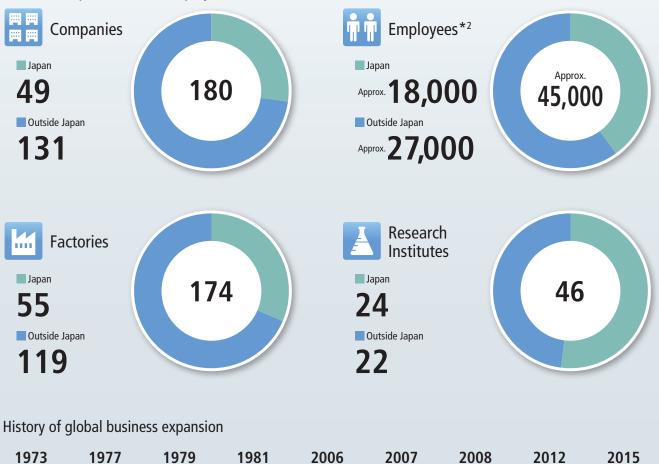
Established in 2011, Otsuka Medical Devices oversees the Otsuka group's medical devices business. Its objective is to grow the business, which operates mainly in Asia, including Japan and China, into one of the group's core businesses. The company is striving to spur further development for the Otsuka group by bringing together the group's medical device experience and expertise to meet new healthcare needs.





### Number of operations and employees

Australia, New Zealand



 
 North America (U.S.)
 Africa (Egypt)
 Western Europe (Spain)
 China
 India
 South America (Brazil)
 Eastern Europe (Czech Republic)
 Turkey
 Australia

\*2 Number of employees at Otsuka Holdings and subsidiaries and affiliates

### Corporate Profile (as of December 31, 2016)

Company Name	Otsuka Holdings Co., Ltd.
Established	July 8, 2008
Capital	¥ 81.69 billion
Head Office	2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan
Tokyo Headquarters	Shinagawa Grand Central Tower, 2-16-4 Konan, Minato-ku, Tokyo 108- 8241, Japan
Telephone	+81-3-6717-1410
Number of Employees	87 (consolidated: 31,787)
Business Description	Control, management and related activities with respect to the Company's subsidiaries and affiliates active in the pharmaceutical industry, nutraceutical industry, consumer products, and other areas.
URL	https://www.otsuka.com/en/

### Shares (as of December 31, 2016)

Number of shares authorized	1,600,000,000 shares
Number of shares issued	557,835,617 shares
Number of shareholders	49,982

### Principal shareholders (top 10 shareholders)

Name of shareholder	Number of shares held (thousand)	Shareholding ratio (%)
The Nomura Trust and Banking Co., Ltd. Otsuka Founders Shareholding Fund Trust Account	62,597	11.55
Otsuka Estate Ltd.	22,891	4.22
Japan Trustee Services Bank, Ltd. (trust account)	21,821	4.02
The Master Trust Bank of Japan, Ltd. (trust account)	16,682	3.07
Otsuka Group Employee Shareholding Fund	14,131	2.60
The Awa Bank, Ltd	10,970	2.02
STATE STREET BANK WEST CLIENT - TREATY 505234	7,735	1.42
GOLDMAN, SACHS& CO.REG	7,486	1.38
Otsuka Asset Co., Ltd.	7,380	1.36
Japan Trustee Services Bank, Ltd. (trust account 9)	6,703	1.23

Notes:

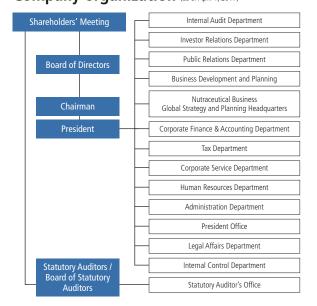
Number of shares held is rounded down to the nearest thousand.

2. Although the Company holds 15,986,347 of its own shares, treasury shares are excluded from the above list.

3. Shareholding ratio is calculated after treasury shares are deducted

### Website information

Investor Relations and Social Responsibility information available on our website

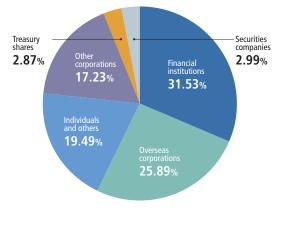


### Company organization (as of April 1, 2017)

About Otsuka

### **Stock distribution**

Distribution of shares by type of shareholder



## • Otsuka Holdings Website https://www.otsuka.com/en/





### Significance of the Corporate Symbol

A symbolic representation of Otsuka group's corporate philosophy, the corporate symbol adopts the initial 'O' of the corporate name as its motif. Representing the sky above, the large 'O' is rendered in gradations of Otsuka BLUE and the small 'O' in Otsuka RED represents the focused energy of Otsuka, the wellspring of these tenets. Offsetting the two forms poised in balance, the Otsuka name is spelled out in an open and friendly typeface. The corporate symbol conveys Otsuka group's energetic commitment to human happiness through good health.





