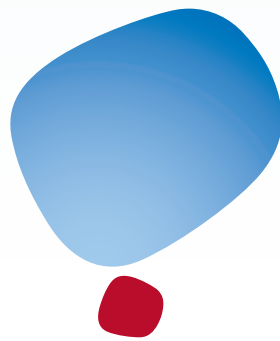


INTEGRATED  
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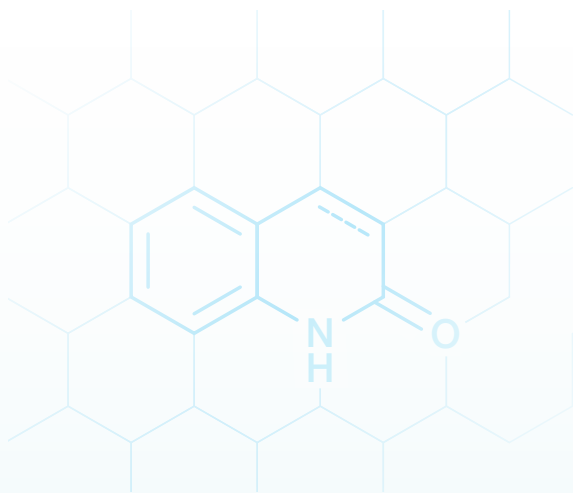
2018

For the year ended December 31, 2018



Otsuka

Otsuka-people creating new products  
for better health worldwide



Otsuka Holdings Co., Ltd.

# The Challenging Spirit, Handed Down

It all began about 100 years ago. The original Otsuka company was established as a manufacturer of raw chemical materials using bittern from the famous salt pans of Naruto, Tokushima Prefecture in Japan, where the founder, Busaburo Otsuka was born. Although it is said that Busaburo had far more land than the average farmer at that time, he wanted to start a business with the aim of making great strides by turning his thoughts to industry. That spirit has been handed down to this day. Against a backdrop of steady business diversification, including entry into the IV solutions business, nationwide and then global expansion, and many decisions, there has always been a challenging spirit at Otsuka that has boldly sought after the unknown. To be satisfied with the status quo, can only mean that creative products and services won't be produced.

We will continue to seek challenges, free from preconceptions.



Second-Generation President  
Masahito Otsuka

Founder  
Busaburo Otsuka

# Innovative and Creative Manufacturing

The Otsuka group of companies has created a whole range of products that only Otsuka can provide. We have pioneered the market with new products such as *POCARI SWEAT*, a health drink that provides unprecedented value, oral anticancer agents, antipsychotics with unique action mechanisms, and the equol-containing food *EQUELLE* to promote women's health and beauty.

We will continue to provide new products and solutions that contribute to the health of people around the world through innovative and creative manufacturing.

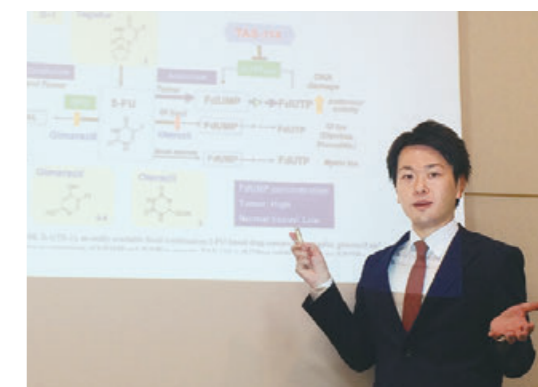
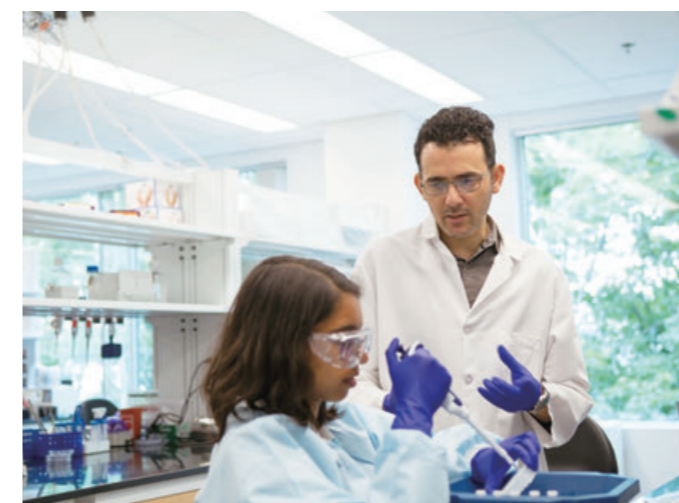


# Otsuka's Grit and Determination

## Challenging Ourselves to See Things Through to the End

The anti-tuberculosis drug *DELTYBA* and the aquaretic and ADPKD treatment drug *Samsca/JINARC\*/JYNARQUE\*\**, which are now widely used around the world, have been brought to market after many years of difficult research and development. *EQUELLE* also, which supports women's health and beauty, was developed after years of research on soybeans with the aim of creating new markets. It took a long time for the value of the now long-popular *ORO-NAMIN C DRINK* and *Calorie Mate* to be recognized. Otsuka has always persistently challenged itself even in unknown fields, starting something and resolving to get results through to the very end. This corporate culture nurtured over many years has been handed down to each and every one of the approximately 47,000 employees working in 30 countries and regions around the world.

\*Brand name for ADPKD treatment in multiple regions outside Japan  
 \*\*Brand name for ADPKD treatment in the U.S.



# Otsuka Originality



## Contributing to Health as a Total Healthcare Company

Based on our enduring mission to contribute to the health of people worldwide, Otsuka is advancing in both the pharmaceutical business, from diagnosis to treatment of diseases, and the nutraceutical business, which helps people maintain and improve day-to-day health. We strive to establish altogether new markets first by developing products grounded in science—not only pharmaceuticals but also nutraceuticals including functional foods and drinks. We then persistently and informatively communicate the novel value of these products.



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 pursue what only we can achieve. The Otsuka group supports the lives of people worldwide through a wide range of innovative and creative products including pharmaceuticals, functional beverages, and functional foods. We are dedicated to cultivating a culture and a dynamic corporate climate reflecting our vision as a health-care company, finding ways to live in harmony with local communities and natural environment from a global perspective, and contributing to more affluent and healthier lives of people.

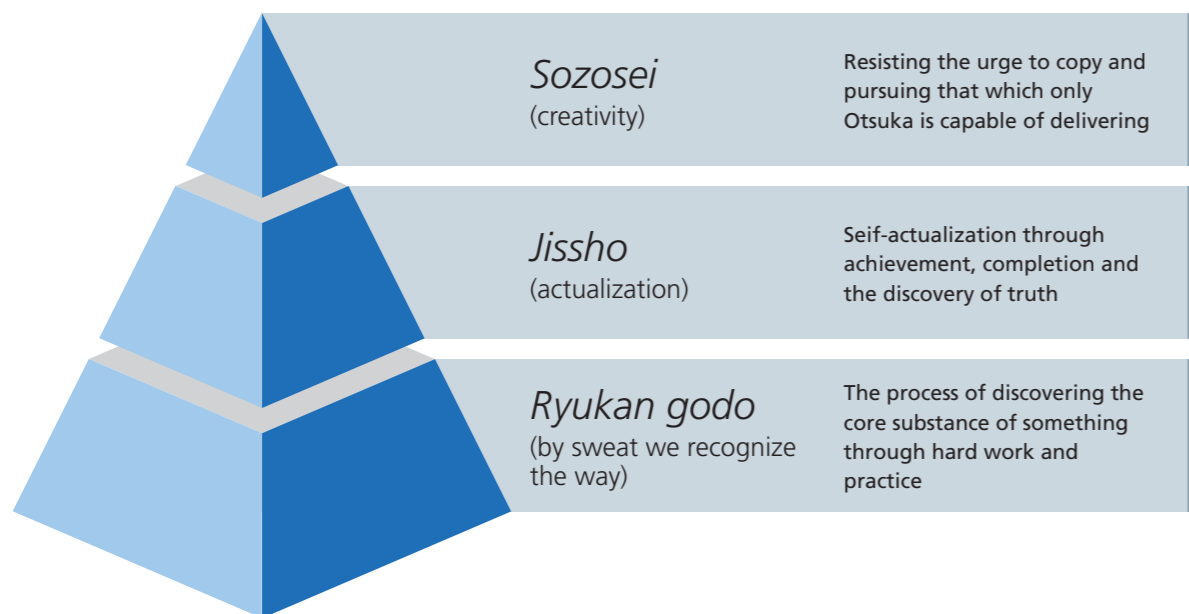
Otsuka's Goal

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

The Otsuka group operates business with the goal of becoming an indispensable contributor to people's health worldwide, fulfilling on our corporate philosophy in every activity. Our operations encompass two core businesses: the pharmaceutical business, which provides comprehensive health support from diagnosis to treatment of diseases, and the nutraceutical business\*, which helps people maintain and improve day-to-day health. We endeavor to create the unchanging value of improving people's health worldwide and continue to provide the value to society.

\*Nutraceuticals=nutrition + pharmaceuticals

Essence of Management



About the Integrated Report

Beginning with the fiscal 2017 edition, Otsuka Holdings has combined its Annual Report and CSR Report into a single integrated report that brings together financial information and non-financial information. We hope it will deepen our stakeholders' understanding of the group's aim to become an indispensable contributor to people's health worldwide. In producing this report, we referred to the International Integrated Reporting Framework advocated by the International Integrated Reporting Council (IIRC) and the Guidance for Collaborative Value Creation developed by Japan's Ministry of Economy, Trade and Industry.

■ Reporting period

Fiscal 2018 (January 1, 2018 to December 31, 2018), with some information after January 2019 included.

■ Scope of Reporting

In principle, this report covers Otsuka Holdings Co., Ltd. and its subsidiaries. Activities and data of more restricted scope are noted in the report.

■ Reference guidelines

- International Integrated Reporting Framework, IIRC
- GRI Standards
- ISO26000
- Environmental Reporting Guidelines (2018 edition), MOE
- Guidance for Collaborative Value Creation, METI, etc.



■ Precautions Regarding Forward-Looking Statements

This integrated report summarizes the operating and financial results of Otsuka Holdings Co., Ltd. and its subsidiaries for fiscal 2018 (January 1, 2018 to December 31, 2018). It also includes information regarding selected material events which occurred between January 1, 2019 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 integrated 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.

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## Message from the President



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

# Creating New Value as a Global, Total Healthcare Company

## — Embracing Challenges based on Our Enduring Mission

Based on our motto and mission, “Otsuka - people creating new products for better health worldwide”, the Otsuka group works hard to create innovative products in order to meet the universal aspiration of people around the world to stay healthy. To this end, we constantly ask ourselves what we can put into practice that only Otsuka can achieve. Contributing to society is also a core tenet of our management and this will help to realize a sustainable one. We will continue to embrace these challenges based on our mission, without being swept by currents of the moment.

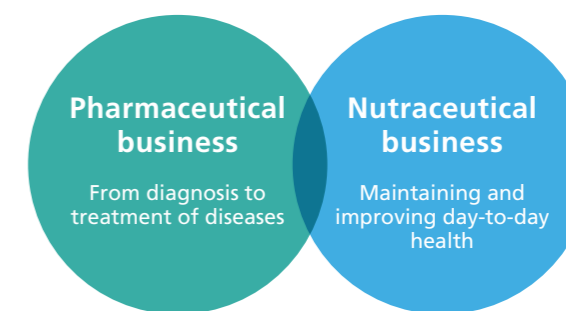
## Our Business Model and Goals

# New innovations through our unique business model

### Business model

The healthcare environment is characterized by expanding medical costs due to aging societies, including medication costs for chronic illnesses, dementia, and cancer; a public-health need to address both treatment-resistant and emerging infectious diseases; and the emergence of new, life-changing health technologies. Partly in response to these developments, penetration of generic drugs and reforms to drug pricing systems have proceeded with increasing speed. Meanwhile, people are growing more interested in daily disease prevention measures based on lifestyle modifications in areas such as nutrition, exercise and rest.

Based on our mission to contribute to the health of people worldwide, the Otsuka group’s activities are based on two pillars: the pharmaceutical business, which extends from diagnosis to treatment of diseases; and the nutraceutical business, which helps people maintain and improve day-to-day health. This business model is based on our belief that healthcare is a whole-body phenomenon that can be fully actualized only if we continue to provide innovative products and services that meet the demands of the times, including the lifestyles evolutions noted above. Therefore, we seek out synergies from collaborations across the multiple group companies to drive innovation and the creation of new markets. We believe this distinctive approach can position us to make tangible contributions to the resolution of health-related social challenges as well.



### Innovation derived from synergies

The core brands of our nutraceutical business—*POCARI SWEAT* and *Calorie Mate*—were born from perspectives, technologies, and know-how gained in our clinical nutrition business, which we have engaged in since 1946. Simultaneously, in our expanding medical device business, we leverage Otsuka’s strengths in pharmaceuticals to exploit new paths in total healthcare. Our diverse business portfolio from foods and beverage to pharmaceuticals addresses whole-body health.

In the pharmaceutical business, various group companies foster flexible, group-wide strategies and decision making. In the nutraceutical business, group companies share information on global health issues and consumer expectations. Both businesses generate first-and-only innovations through our unique approaches that seek to leverage Otsuka’s soft and hard assets across the group companies. Soft assets include corporate culture and philosophy as well as deep and ingrained knowledge based on a nearly 100-year history and a committed workforce that is passionate about our aims. Hard assets include advanced technologies and an infrastructure spanning the globe.



The Global Committee for the Nutraceutical Business

### Indispensable contributor to people's health worldwide

Our business environment is undergoing significant changes that will impact all that we do. These changes include advances in basic science that influence disease-treatment systems, a profusion of information and data, and other broad societal evolutions such as in people's expectations, lifestyles and social circumstances.

In this shifting context, there are many things that only Otsuka can achieve. For example, digital technology, data and information open the opportunity for deeper insights in areas such as how diseases and treatments affect individual patients, and on how consumers balance considerations of product flavor and healthiness. However, that obligates us to use the insights responsibly on behalf of society as well as the company, and also protect individual privacy.

Deploying Otsuka's uncommon management style and principles, we will continue to deliver sustainable growth to help to address healthcare challenges, in our quest to become an indispensable contributor to people's health worldwide.

### Otsuka Values

## Distinctive corporate culture cultivated over many years, and its outcomes

### Nucleus of our corporate culture

The foundation of the Otsuka group's business is its corporate culture. The three important principles of this culture are *Ryukan Godo* (commitment), *Jissho* (actualization), and *Sozosei* (creativity).

*Ryukan Godo* is a term coined by *Busaburo Otsuka*, the founder of the Otsuka group. It means that one can discover the core substance and truth of matters only through hard work and practice. *Jissho*, the main principle conveyed by Masahito Otsuka, a second-generation leader, is



Ryukan Godo: A calligraphic work by Otsuka founder, Busaburo Otsuka



Monument engraved with our corporate philosophy (Tokushima Prefecture, Japan)

Overview of Second Medium-Term Management Plan

→ p.16~

self-actualization and the discovery of truth through achievement and completion. In the case of pharmaceuticals, *Jissho* (actualization) only occurs when a drug is approved and reaches the patient. *Sozosei*, a term used by Akihiko Otsuka, the third-generation leader of the group of companies, is based on a determination to pursue only what Otsuka can achieve, without imitation. It underscores our policy of creating innovative products that defy existing preconceptions.

### Realizing *Ryukan Godo*, *Jissho*, and *Sozosei*

Our policy is to use our own hands and sweat to find the essence of solutions, without imitation—to develop, launch, and secure our products in the market.

For example, *Samsca/JINARC/JYNARQUE*, a revolutionary aquaretic agent that took 26 years to develop, resulted from research that began with a physician's request: "I want a diuretic that excretes only water." After many years of hard work, *Samsca/JINARC/JYNARQUE* was made available to patients as the world's first treatment of autosomal dominant polycystic kidney disease (ADPKD), an inherited disease that did not have any therapeutic treatments.

In the nutraceuticals area, *POCARI SWEAT* was developed as a beverage to easily replenish water and electrolytes (ions) lost through sweating. When launched in Japan, it was one of the few beverages that broke through established market preconceptions. Sold in an unusual blue-colored can, it had a relatively light taste for that time, so it took a while to gain the acceptance of consumers. To emphasize the value of the new drink, all employees conducted sampling sessions to help consumers experience the effect. As a result of these meticulous efforts, we firmly established our brand and created the completely new ion drink market in Japan.

### Medium-Term Management Plan

## Overview of Second Medium-Term Management Plan

### Diversify revenue structure to achieve sustainable growth

During our First Medium-Term Management Plan (fiscal 2009-2013), we maximized the value of the antipsychotic agent *ABILIFY*. In our Second Medium-Term Management Plan (fiscal 2014-2018), during which the *ABILIFY* patent expired, we determined that our most important priority had to be diversification of our revenue structure. Therefore, during the plan period we strengthened and broadened each of our businesses as revenue pillars, and built a foundation that will support the group's sustainable growth.

### Second Medium-Term Management Plan: Outcomes and issues

In the pharmaceutical business, where we sought to reinforce our therapeutic franchises, we enjoyed steady growth of newer global products, including *ABILIFY MAINTENA*, *REXULTI*, and *Samsca/JINARC/JYNARQUE*. As a result, we rebuilt a robust revenue foundation and made significant progress toward maximization and investment of cash flows in these growing core

businesses. In the nutraceutical business, we made reforms that have consistently delivered operating profit margin of ten percent or higher. Thanks to these efforts, we achieved the objective to rejuvenate the product portfolio, moving that business toward more sustainable growth.

On the other hand, we have also encountered a number of hurdles. Our business environment in Japan has become more challenging due to dramatic reforms of the drug pricing system and stepped-up measures to promote the use of generic drugs. In addition, we are creating many entirely new drug offerings in areas with no therapeutic precedent or market, such as *JYNARQUE*, and *ABILIFY MYCITE*, the first-ever digital medicine. Development and commercialization processes can be just as unprecedented as the products themselves. In light of these challenges, we believe a key priority will be to maximize corporate value by anticipating major changes taking place in our business environment.

Outline of  
Third Medium-Term  
Management Plan

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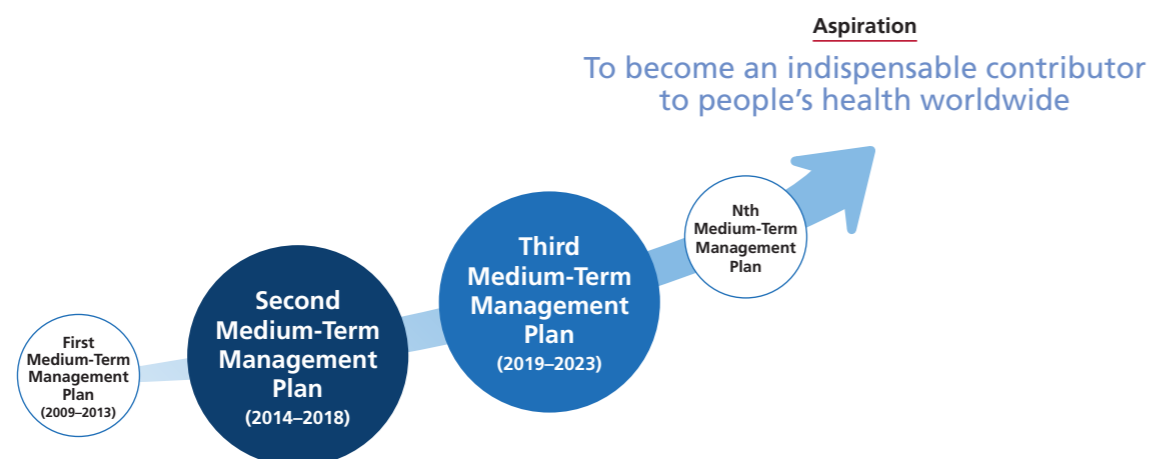
### Outline of Third Medium-Term Management Plan

The Third Medium-Term Management Plan (2019–2023) is a period in which to advance and grow in the global market as a total healthcare company.

We will focus on maximization of existing business value from expansion of the global products *ABILIFY MAINTENA*, *REXULTI*, *Samsca/JINARC/JYNARQUE* and *LONSURF*, which formed a strong basis on the Second Medium-Term Management Plan.

In addition, we will create new value by challenging ourselves in new modalities, categories, and geographies. Contingent on regulatory approvals, late-stage candidates in new therapeutic areas will become revenue drivers: *Avanir Pharmaceutical's AVP-786*, in development for several mental health disorders; and *vadadustat*, in development for anemia secondary to chronic kidney disease, in collaboration with *Akebia Therapeutics*. In the nutraceutical business, the aim is to grow the *Nature Made* line by leading the supplements sector with vitamin products tailored to the needs of individual consumers. *Daiya Foods*, with a portfolio of delicious, plant-based foods, will further expand its product line and distribution channels that appeal to millennial consumers. These investments in future growth will be balanced by a disciplined focus on profit margins, and therefore shareholder returns.

The Third Medium-Term Management Plan period will be a time of sustainable growth as the seeds planted during the Second Medium-Term Management Plan period sprout and become large trees.



## Human resources sought by Otsuka

# People who embrace challenges with determination

### Respecting diversity

The Otsuka group consists of 189 companies with around 47,000 employees worldwide, more than half of whom are overseas employees. We aim to be a company in which all of our diverse employees can excel, regardless of nationality and other differences. This requires a corporate culture in which employees can feel fulfillment in finding new values through mutual acknowledgment and active acceptance of different backgrounds, mindsets, and traditions, as well as the occasional clash of differing perspectives. Otsuka has embraced diversity since the 1980s, before the concept had taken hold in Japan and elsewhere, and actively utilized a diversity of human resources.

### Encouraging challenges

In Otsuka, we have an embedded culture based on taking on challenges—doing what other companies choose not to do. The fact that nobody else has tried something is just the type of challenge that we need and use to invigorate our organization. Starting from scratch, we need to consider how to proceed and form a hypothesis. Then, we move into action and once started, work with sticky resolve until the end. We believe this approach leads us to subsequent challenges, and also to growth.

For those willing to embrace such challenges, Otsuka provides a culture of active support. First of all, responsibility. People who have been given responsibility will feel much more committed and responsible than those who have not. Accumulation of such experiences results in personal development.

### Develop executives to lead the company

As CEO, one of my personal areas of focus is the development of executive human resources to lead the company in the future. Business management equates to people, and will not work out if people don't grow. Otsuka will celebrate its 100th anniversary in 2021. In order to grow creatively and sustainably over the next 100 years, I believe that cultivation of human resources, especially next-generation leadership, is extremely important—on a par with making medium- and long-term capital investment.

For this reason, in 2016 Otsuka Holdings opened the Otsuka Global Academy, which conducts executive human resource development programs based on swiftly identifying and then fostering future leaders who in turn support the development of other employees.

Specifically, it has three programs for Otsuka group employees—the Senior Leadership Program, the Middle Leadership Program, and from now, a Global Leadership Program for upper-middle level managers in Otsuka group companies around the world. More than 100 employees have participated to date. The programs convey not only the latest managerial knowledge and skills, but also emphasize the continuity and relevance of business approaches practiced successfully since our founding. This includes the managerial and leadership styles of successive generations of Otsuka leaders, how they perceived the business, and case studies of their successes and failures.





Executive Human Resource Development Program

Discussions also center on the type and qualifications of human resources required for leadership, and effective decision-making methods.

The Academy should be a place where participants feel and learn directly from those discussions. I hope that each participant completes their program with an understanding of Otsuka's true nature and a sense of ownership that is then reflected in their work. I also want participants to convey what they felt and learned at the Academy to their fellow employees.

From the time I was a young employee at Otsuka, I have often asked myself "What is the value of this company?" As a result of learning many things from my predecessors, I have come to find my own answers. Now, as a teacher in the training programs, I pass on my findings to employees who are now the age I was when I was struggling to answer the question.

In 2018, I spent more than a month on human resource development, including preparation time and traveling. There are many things that I too can still learn by thinking and engaging with my younger colleagues in serious discussions on each business based on multiple perspectives. I want to continue to teach and learn hand in hand with those who will lead the company.

## CSR activities integrated with our businesses

# Pursuing the contributions only Otsuka can make to help realize a sustainable society

### Adhering to our corporate philosophy to help realize a sustainable society

*DELTYBA*, one of the world's first new anti-tuberculosis drugs in 50 years, is used in over 80 countries worldwide today, addressing drug-resistant tuberculosis, a serious public health problem, especially in areas with inadequate health systems.

WE SUPPORT



We define CSR in a broad sense as being an integrated part of our business. We don't promote sustainability along with our businesses, but through it. Our pharmaceutical and nutraceutical products themselves, are created and produced to help people maintain and improve their health, and to realize a better life. We aim to simultaneously achieve our own sustainable growth and a healthy, sustainable society.

Enabling access to products such as *DELTYBA*, mentioned above, we constantly pursue activities aimed at contributing in ways that only Otsuka can.

In November 2016, Otsuka Holdings became a signatory to the United Nations Global Compact. As a signatory, we express our support for the Global Compact's ideals while at the same time helping achieve the Sustainable Development Goals (SDGs) adopted at a United Nations summit. In this way, we reaffirm the Otsuka group's commitment to working with society in order to achieve sustainable development.

### Risk preparedness

Preparing for risk is also important for sustainable corporate growth. As a healthcare company involved with people's lives, product quality is essential to our business, and we work continuously to maintain and improve quality throughout the value chain. With this in mind, Otsuka Pharmaceutical made its quality assurance department independent from its production department, headed by an executive director-level leader.

We also hold global product quality meetings, where around 100 participants, including managers and heads of quality control, meet to discuss quality issues and future-oriented initiatives. In addition to conducting internal audits at each plant regularly, we strive to ensure the reliability of our data. Specifically, we have introduced a computer system to prevent important documents and data related to quality and production from being falsified.

To maintain and improve the compliance-related awareness of all employees around the world, we have produced universal training materials that conform to the Otsuka group's Global Code of Business Ethics and its Global Anti-Corruption Policy. All employees attend the training annually. Compliance violations can have a profound impact on the survival of a company. For this reason, we promote continuous, global measures to ensure that each and every employee engages in work based on high ethical standards.

What I consider Otsuka's biggest risk would be to forget our roots. Without deep and steadfast roots, trees cannot grow large. That is why we must go about our daily activities without forgetting what we learn from three important principles of our corporate culture: *Ryukan Godo* (commitment: by sweat we recognize the way), *Jissho* (actualization), and *Sozosei* (creativity).

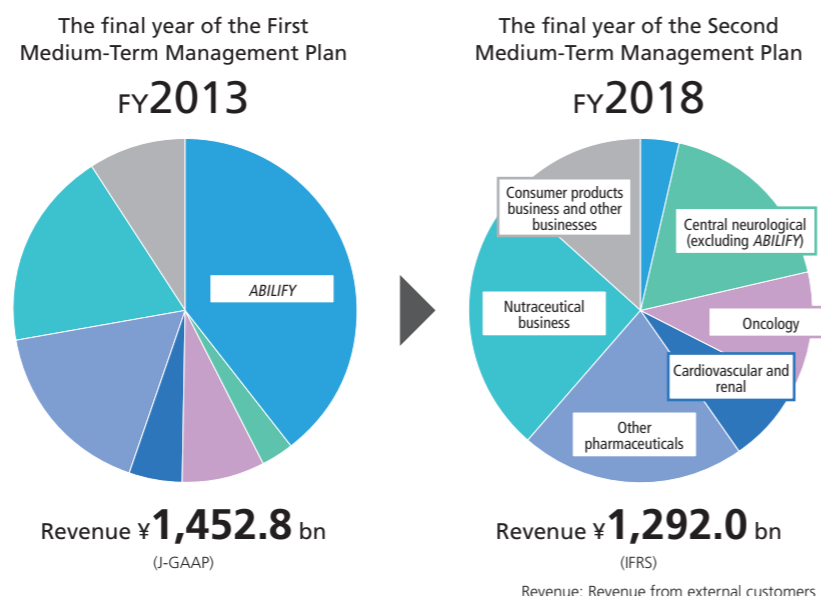
# Review of the Second Medium-Term Management Plan

## Establishing diversified revenue structure to achieve sustainable growth

The second medium-term management plan (hereinafter referred to as the "Plan") with fiscal 2018 as its final year sets the highest priority to diversifying the Group's revenue structure to achieve sustainable growth. In the pharmaceutical business, we have pursued strengthening our core therapeutic franchises. In the nutraceutical business (hereinafter referred to as the "NC business") we have pursued business transformation and structural reform to achieve growth.

### Establishing a Diversified Revenue Structure

Facing the end of the exclusive sales period for ABILIFY, the Group's main product, we have pursued diversifying our revenue structure to achieve sustainable growth. Through investing aggressively for growth and making strategic alliances, each business area has grown steadily led by new product lines, and as a result we have achieved our top priority of diversifying sales and earnings structure.



## Pharmaceutical Business

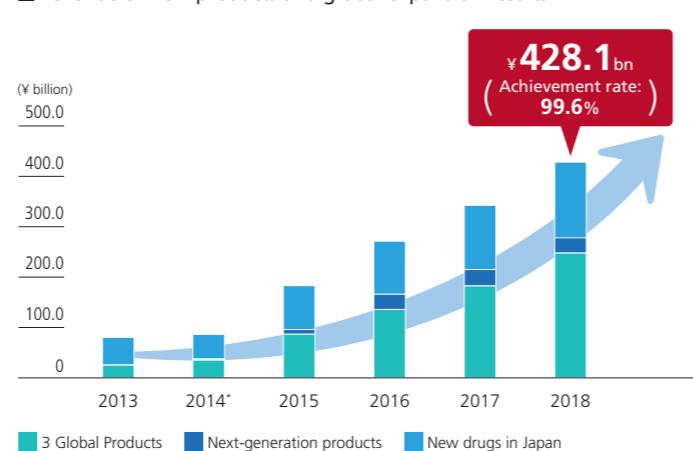
### Maximizing Product Value

- Achieved 99.6% of Target Sales Revenue for New Product Lines
- Building Foundation to Continue to Drive the Group's Regrowth

Under the Plan, we categorized the antipsychotic agent (long-acting injectable) ABILIFY MAINTENA, antipsychotic agent REXULTI, and V<sub>2</sub>-receptor antagonist Samsca/JINARC/JYNARQUE into "the global 3 products," the anti-cancer agent LONSURF into "the next-generation product," and new drugs launched after 2009 in Japan into "Domestic new products," all of which are considered growth drivers. During the plan period we have actively invested our management resources into their approvals, addition of new indications, and expansion of sales areas for the early maximization of their product values.

As a result, the total revenue of these new product lines in fiscal 2018 increased to 428.1 billion yen, 99.6% of the initial target (430 billion yen), and we have successfully established the foundation that will strongly drive the Group's re-growth after the Plan.

Revenue of new products and global expansion results



\*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.

## Active R&D Investment in Core Therapeutic Areas

### Strengthened Product Franchises in Core Therapeutic Areas for Sustainable Growth

Under the Plan, we continued active investments in R&D, working to strengthen our drug discovery capabilities and maximize the value of our new product lineup that drives growth, with a focus on core therapeutic areas. At the same time, we have invested in outside projects which would bring synergies with our existing know-how and intellectual assets and enhanced our development pipeline. Combining these efforts we have moved our R&D activities forward for ensuring our future sustainable growth and contributing to social issues.

#### Psychiatry and Neurology

— Full-scale entry into the neurologic area and strengthening of the psychiatric area

- Full-scale entry into the area of neurology through the acquisition of Avanir Pharmaceuticals.
- Acquisition of clinical development capabilities that have created an untapped market for pseudobulbar affect (PBA)
- Acquired a product under development AVP-786 for agitation associated with Alzheimer's
- Expansion of CNS business through merger with Otsuka's assets in the psychiatric area

TEVA: Licensed fremanezumab (Japan), a prophylactic migraine drug candidate, from Teva Pharmaceutical Industries

Abilify MyCite: World's first digital medicine system, Abilify MyCite<sup>®</sup> approved (U.S.)

Neurovance: Acquired Neurovance and obtained ADHD therapeutic development drug, centanafadine

#### Oncology

— Established a group-wide drug discovery platform and introduced new therapeutic technologies

- Strengthened in-house drug discovery capabilities
- Strengthened inter-group drug discovery collaboration system centered on Taiho Pharmaceutical and Astex Pharmaceuticals
- Acquired development and marketing rights in Asia for an adenosine receptor antagonist from Arcus Biosciences

Arcus Biosciences: Business entry in genetically modified T cell therapy

Takara: Signed a joint development and exclusive sales contract with Takara Bio for the gene therapy drugs, NY-ESO-1 siTCR<sup>®</sup> and CD19 CAR (Japan)

Osaka University: Obtained exclusive development, manufacturing and marketing rights worldwide for MMG49 CAR-T cell therapy from Osaka University

#### Cardiovascular and Renal

— Developed as the next-generation core area

- Licensed vadadustat, a drug under development for renal anemia, from Akebia Therapeutics
- Acquired antibody platform technology and kidney disease-related pipeline through acquisition of Visterra
- Expanded global investment in medical device business
- Acquired an ultrasound renal denervation treatment device and its technology platform through acquisition of ReCor Medical
- Acquired arterial stent business foundation and cutting-edge products through acquisition of Veryan Medical

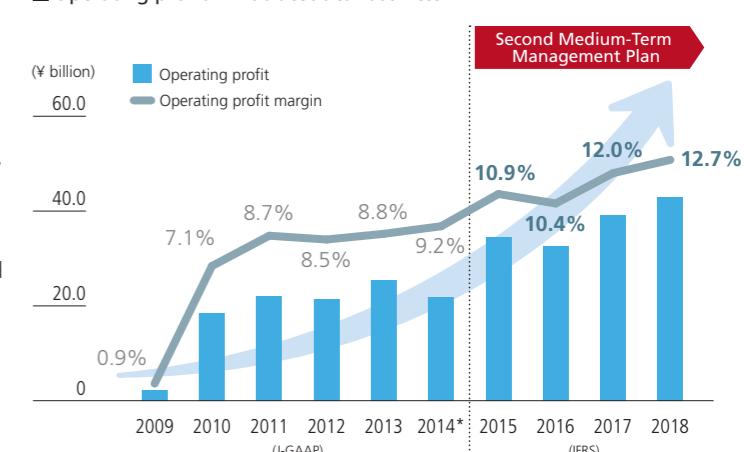
## NC Business

### Improved Profitability

In the NC business, we have pursued the fundamental reforms of our business practices through reviewing our business assets and the implementation of the two strategies; accelerating global expansion and developing new products.

We have reviewed our business practice based on various value chains and focused on the development of ingenious new products contributing to the extension of healthy life expectancy, the improvement of product value utilizing scientific evidences and our experience cultivated in pharmaceuticals, and the promotional activities helping our customers to recognize health benefits of our products. We have also accelerated the global expansion of our core brands including POCARI SWEAT and ORONAMIN C DRINK; and entered into the plant-based business through the acquisition of Daiya Foods. Through these efforts the Group has achieved an operating margin of over 10% ahead of schedule and established a business structure necessary to constantly maintain this level of operating margin.

Operating profit in nutraceutical business



\* 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.

### Accelerating Global Expansion

#### Asia

- POCARI SWEAT: Established subsidiaries in Thailand and Philippines to strengthen sales
- ORONAMIN C DRINK: Started local production and sales in Indonesia
- SOYJOY: Started local production in Indonesia

#### North America

- Plant-based foods: daiya: Entered the plant-based food sector by acquiring Daiya Foods
- Nutritional supplements: MegaFood: Entered the natural foods channel through the acquisition of FoodState
- EQUELLE: Started roll out in the U.S. market

#### Europe

- Nutrition & Santé: Strengthened production system for 'free-from' products

# Outline of the Third Medium-Term Management Plan

## Advance in the Global Market as a Unique Total Healthcare Company

### —Five-Year Growth Phase—

Our corporate philosophy is “Otsuka—people creating new products for better health worldwide,” and we practice our management spirits of “*Ryukan-godo*” (Commitment), “*Jissho*” (Actualization), and “*Sozosei*” (Creativity). Following these philosophy and spirits, Otsuka has been creating new values by engaging in various unique business, identifying true insight needs around the world, creating new concepts and products by effectively combining science and technology, mixing various existing businesses and their spin-outs, and pioneering in untouched niche areas. We define the Third Medium-Term Management Plan as a five-year period of growth and establishing ourselves as a unique total healthcare company in the global market. Focusing on our core businesses of pharmaceutical and nutraceutical we are going to maximize values of existing business and create new values while practicing the business management with a corporate wide awareness of capital costs.

### [ Performance Targets ]

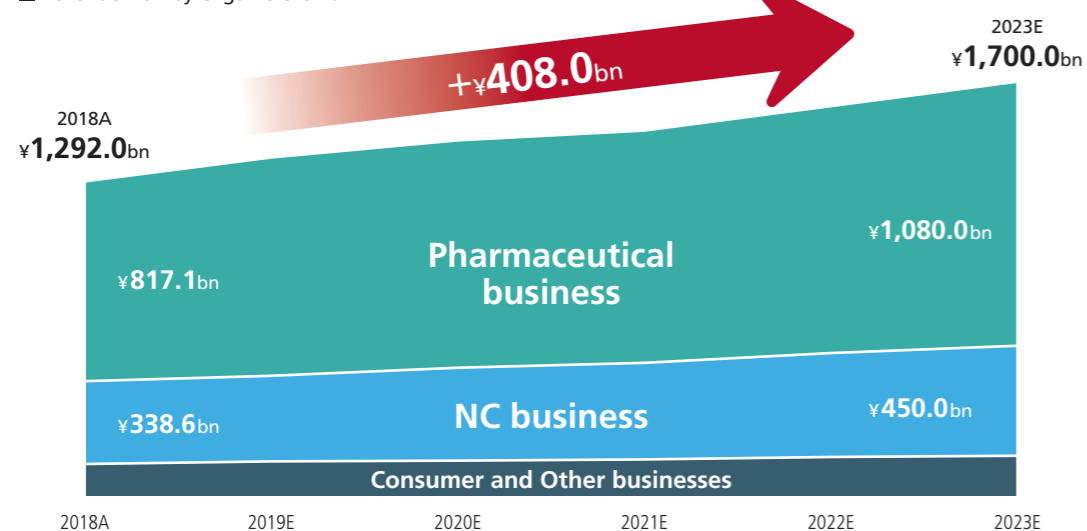
#### Business Profit CAGR of 10% or More

Helped by organic growth of existing businesses in the pharmaceutical and NC businesses, in the plan our sales revenue will reach 1,700 billion yen in fiscal 2023 (the final year of the plan), an increase of 408 billion yen from 2018, and our business profits before R&D expenses will reach 460 billion yen, both of which are our record highs. Our target business profit for fiscal 2023 is set for 200 billion yen with CAGR 10% or more. In addition, we will continue to actively invest in research and development for sustainable growth.

	2018A	2021E	2023E	CAGR 2018A-2023E
Revenue	1,292.0	1,500.0	1,700.0	5.6 %
Business profit before R&D expenses	313.8	390.0	460.0	7.9 %
Ratio/Revenue	24.3%	26.0%	27.1%	
R&D expenses	192.9	230.0	260.0	6.1 %
Business profit	120.9	160.0	200.0	10.6 %
Ratio/Revenue	9.4%	10.7%	11.8%	
ROE	4.7%	≥6.0%	≥8.0%	

Note: Exchange rate assumptions ¥110/\$, ¥130/euro  
 Not including performance growth by strategic investments (M&A etc)  
 Business profit = Revenue - COGS - SG&A + Share of profit of associates - R&D expenses

Revenue Plan by Organic Growth



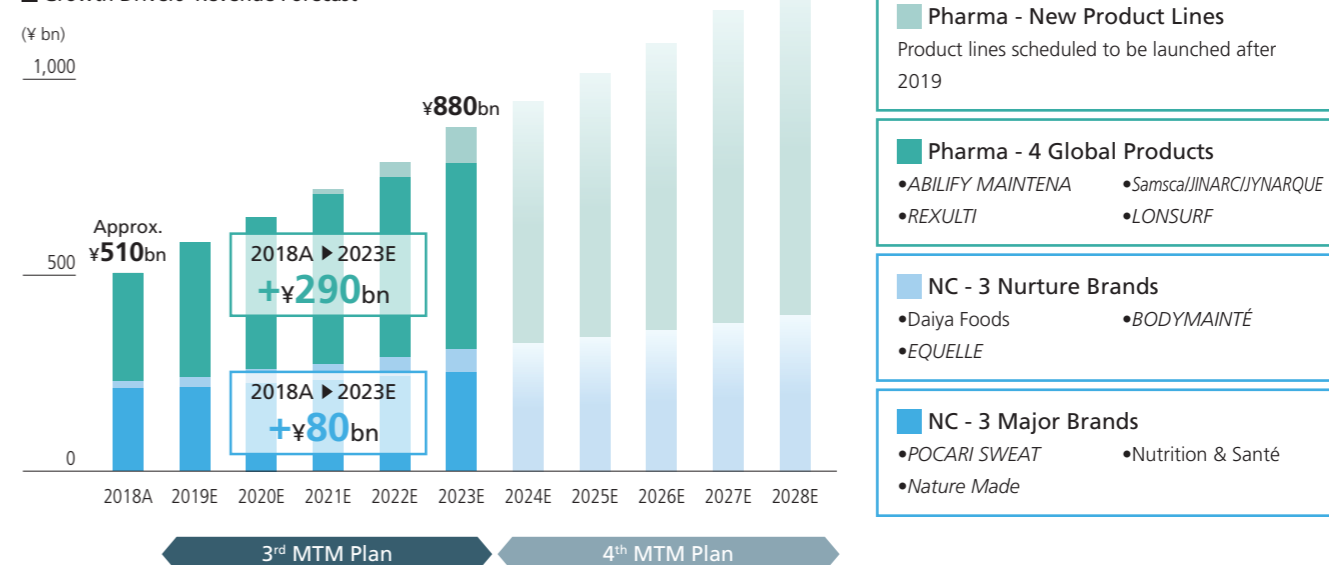
\* Revenue from external customers

### [ Business Strategy ]

#### Maximizing Existing Business Value and New Value Creation

Otsuka will enhance strategic initiatives upon designating the following products and brands as growth drivers, namely; four global products in pharmaceuticals (*ABILIFY MAINTENA*, *REXULTI*, *Samsca/JINARC/JYNARQUE*, and *LONSURF*), three major brands (*POCARI SWEAT*, *Nature Made*, and Nutrition & Santé), and three nurture brands in NC business (*Daiya Foods*, *EQUELLE*, and *BODYMAINTÉ*). Additionally, Otsuka will launch and nurture new product lines that will drive sustainable growth in the pharmaceutical and NC businesses.

Growth Drivers' Revenue Forecast (¥ bn)



Business Category	Strategy
Pharmaceutical Business	<ul style="list-style-type: none"> <li>Maximize Values of Existing Businesses</li> <li>Challenge New Frontiers that “Only Otsuka Can Do”</li> <li>Generate Innovation From Creative and Diverse Research Platforms</li> </ul>
Nutraceutical Business	<ul style="list-style-type: none"> <li>Create New Concepts Keeping an Eye on Changes in the Environments</li> <li>Challenge to New Categories and New Areas</li> <li>Continuous High Profit Structure</li> </ul>

### [ Financial Policy ]

#### Business Management with a Corporatewide Awareness of Capital Costs

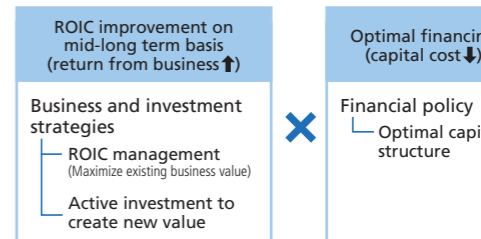
Otsuka is going to implement the business management with a corporatewide awareness of capital costs during this mid-term period and promote it throughout the Group.

In business and strategic investing, Otsuka will work to improve its return on invested capital (ROIC) for a medium- to long-term time horizon by monitoring its ROIC while actively investing for new value creation.

In financing activities, Otsuka will secure necessary funds for growth investments while considering the optimal capital structure.

Through these efforts, we aim to maximize our corporate value.

- Awareness of capital costs reflecting business risks
- Performance assessments taking into account capital costs



Presentation materials for the Third Medium-Term Management Plan are available on the Otsuka Holdings website.

<https://www.otsuka.com/en/ir/library/presentation.html>



Feature

# Access to

## Fight against Tuberculosis— An Old Disease with a New Face

Global public health improved thanks to *DELTYBA*, a tuberculosis drug

The United Nations (UN) Millennium Development Goals (MDGs) were adopted in 2000. Among the MDGs, the goal to combat HIV/AIDS has made great progress. Then, in 2015, the UN announced its Sustainable Development Goals (SDGs), which inherit the ideals of the MDGs, and embarked on new initiatives to achieve these goals. Deploying its tuberculosis drug, *DELTYBA*, the Otsuka group is seeking to eliminate tuberculosis, which is listed as target 3.3 in the SDGs, and also contribute to improvement of global public health.

### What is tuberculosis?

It is an airborne infectious disease where tuberculosis mycobacteria enter the body and multiply, mainly in the lungs, resulting in symptoms such as coughing and production of sputum. In serious cases, the infection can cause breathing difficulties and affect other organs, potentially resulting in death. While highly contagious, the disease takes hold in 5–10% of cases, and may develop several years after infection due to a weakening immune system.



# Medicine

### SDGs target 3.3

By 2030, end the epidemics of HIV/AIDS, **tuberculosis**, malaria, and neglected tropical diseases and combat hepatitis, water-borne infections, and other communicable diseases



### Number of individuals infected with mycobacterium tuberculosis

Approx. **1.7** billion

### Annual deaths from tuberculosis

Approx. **1.3** million

### Tuberculosis still spreading worldwide

Tuberculosis is still spreading worldwide. Tuberculosis is one of the world's top three infectious diseases, along with malaria and HIV/AIDS. Approximately 10 million people develop tuberculosis each year, of whom around 1.3 million die\*, making it the leading cause of death among infectious diseases. Moreover, tuberculosis is highly contagious. About 1.7 billion people are said to be infected with mycobacterium tuberculosis (M.TB) bacteria out of a global population of 7 billion.

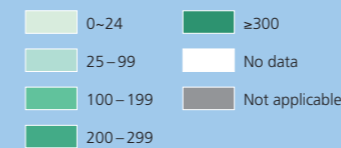
M.TB, which may develop into active tuberculosis disease, is a very "stubborn bacterium," and patients who have contracted the disease must continue taking multiple medications in combination, sometimes for six months or more due to drug-resistant strains. TB is prevalent in many low- and middle-income countries and low-resource settings. Because tuberculosis requires long-term treatment, it represents a major economic challenge in high-burden countries.

\* WHO Global Tuberculosis Report 2018

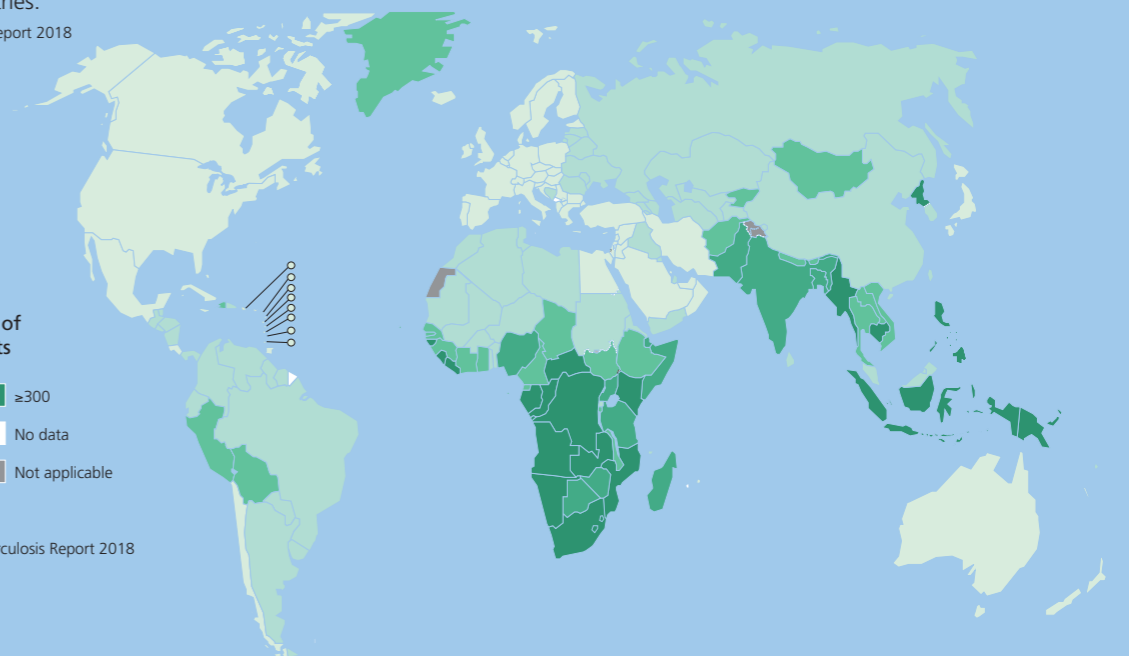
### Limitations of conventional medicinal treatment.

Currently, multiple drugs are used to treat tuberculosis. If only one drug is administered, the bacteria become resistant to it, so treatment usually involves administering three to four drugs. In most cases, drug-sensitive tuberculosis can be successfully treated with first-line drugs and proper case management. In recent years, however, the emergence of resistance to tuberculosis drugs has become widespread. Discontinuation of medication for some reason, such as irregular doses or side effects, gives rise to bacteria that are resistant to the drugs that have been taken. Among these are multidrug-resistant tuberculosis (MDR-TB) bacteria that have become resistant to rifampicin and isoniazid, the two most potent first-line therapeutic agents. Extensively drug-resistant tuberculosis (XDR-TB) is resistant to an even greater number of drugs, representing a major global challenge in the campaign to control the disease.

### Global Distribution of Tuberculosis Patients



Reference: WHO Global Tuberculosis Report 2018



## DELTYBA is improving global health



# One of the first new drugs in 50 years

### Birth of DELTYBA

“If nobody does it, Otsuka must do it.”

DELTYBA received approval for the treatment of MDR-TB in 2014. It has a completely different mechanism of action compared with previous therapeutic agents, and is also effective against tuberculosis bacteria that have become resistant to existing drugs. Therefore, it is expected to play a role as a therapeutic drug for MDR-TB which is becoming more and more serious. In 2015, DELTYBA was included in the WHO Model List of Essential Medicines (list of priority drugs in any country).

DELTYBA is one of the newest tuberculosis drugs approved in the world in the last 50 years. Although MDR-TB is currently gaining prominent attention, tuberculosis research was regarded as “out of fashion” in the pharmaceutical industry until recently. That is because after rifampicin was discovered in 1964 it was thought that tuberculosis had become a treatable disease. In the 1970s, when many researchers and research institutes around the world stopped development, Otsuka was the only company to continue research, based on the belief that “Tuberculosis is a serious global health problem, and we must continue our research if nobody else does it.” DELTYBA was created after more than 30 years of such research activities. Otsuka Pharmaceutical remains actively engaged in R&D on new tuberculosis



drugs. According to a 2017 report published by the Treatment Action Group (TAG), a patient advocacy group for combating HIV/AIDS and tuberculosis, Otsuka Pharmaceutical was the largest private funder of TB research and development.

#### Top Ten Funders of TB Research in 2017

Funding Organization	Sector	Total (USD)	Percent of Total Funding
1 U.S. NIH	Public	245,461,895	32%
2 Bill & Melinda Gates Foundation	Philanthropic	127,953,459	17%
3 USAID	Public	33,989,472	4%
4 Unitaid	Multilateral	28,556,016	4%
<b>5 Otsuka Pharmaceuticals</b>	<b>Private</b>	<b>22,773,887</b>	<b>3%</b>
6 U.K. DFID	Public	20,642,634	3%
7 Company X	Private	20,550,920	3%
8 European Commission	Public	19,275,723	3%
9 U.S. CDC	Public	18,256,200	2%
10 EDCTP	Public	17,708,217	2%

#### DELTYBA Research History

1964	rifampicin was discovered as standard treatment for tuberculosis
1971	Otsuka Pharmaceutical commenced drug discovery research to work on infectious disease as one its key themes
<b>1982</b>	<b>Full-scale research into tuberculosis drugs was started</b>
2004	Clinical trials were started for OPC-67683 (later DELTYBA) for the treatment of tuberculosis
2014	DELTYBA was approved and launched in Europe and Japan as a therapeutic drug for multidrug-resistant tuberculosis (MDR-TB)
2015	DELTYBA was added to WHO Model List of Essential Medicines
2016	Agreement was concluded with the Stop TB Partnership's Global Drug Facility (GDF).
2017	Licensing agreement was executed with R-Pharm of Russia for the manufacture and commercialization of DELTYBA in the Russian Federation and 12 surrounding countries
2017	Licensing agreement was executed with Mylan of India to expand DELTYBA approval and commercialization activities in high-burden countries



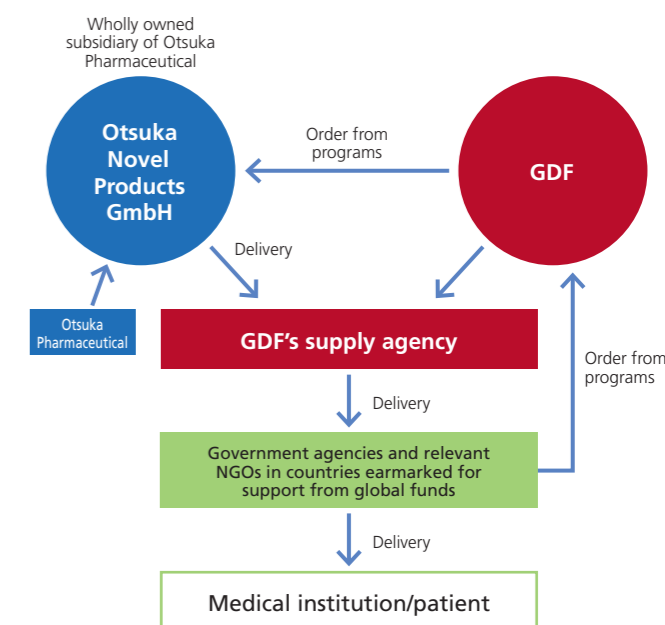
## External Collaborations

### Expanding access to tuberculosis drugs in low-income countries in collaboration with the Stop TB Partnership's Global Drug Facility (StopTB/GDF)\*

DELTYBA is one of the first new tuberculosis drugs approved in the last 50 years, but this is meaningless if the drug is not accessible to patients. That said, there are many tuberculosis patients in developing countries of Africa, Asia, and other regions where the Otsuka Group does not have a business base. For this reason, we began working with the Stop TB Partnership's Global Drug Facility (StopTB/GDF), an organization dedicated to expanding access to quality-assured tuberculosis drugs and diagnostic agents and ensuring the sustainable procurement of those drugs in developing countries. StopTB/GDF now supplies DELTYBA to more than 80 countries, and more than 70% of patients currently taking this drug receive their medicines procured by StopTB/GDF, highlighting the organization's excellent contribution to expanding access.

\* Founded in 2001, the Stop TB Partnership has a mission to serve every person who is vulnerable to tuberculosis and to ensure that high-quality diagnosis, treatment and care are available to all who need it. StopTB/GDF is the largest global provider of quality-assured anti-tuberculosis medicines, diagnostics, and laboratory supplies to the public sector while also providing technical assistance to TB programs and supporting wide use of innovative tools.

#### DELTYBA: Supply route via StopTB/GDF



### Topics

#### Cooperation with Japanese government on DELTYBA

We also cooperate with and receive support from the Japanese government in various ways. These include support with access initiatives overseas to sharing educational information at international conferences and events.



One of the eight items in the economic cooperation plan agreed to by Japanese and Russian leaders is improving medical care and promoting healthy life spans. At the Eastern Economic Forum held in Vladivostok on September 7, 2017, Japan's Prime Minister, Shinzo Abe, made a speech about mutual cooperation aimed at getting swift approval for DELTYBA in Russia. In that speech, he said, "In the fight against tuberculosis, Japan and Russia have joined hands."



At a United Nations General Assembly High-Level Meeting on Tuberculosis held in New York City on September 26, 2018, Katsunobu Kato, Minister of Health, Labour and Welfare, gave a speech on developing treatments for multidrug-resistant tuberculosis in Japan and contributing to eradication of the disease worldwide, and at the same time adopted the political declaration toward eliminating tuberculosis.

DELTYBA is improving global health



## Establishing a supply network which will save patients around the world



### Expanding access to patients worldwide

Numerous collaborations have been formed to combat tuberculosis and other diseases that threaten global health, such as with the WHO, United Nations, and various national governments who provide active support. In addition to its aforementioned cooperation with GDF, Otsuka Pharmaceutical contributes to the health of people around the world through various collaborative initiatives with its many stakeholders. These include our participation in the Global Health Innovative Technology Fund (GHIT), a Japanese public-private partnership established to address infectious diseases worldwide, as well as cooperation with programs spearheaded by Médecins Sans Frontières/Doctors Without Borders (MSF). We have also obtained support from the Bill & Melinda Gates Foundation for the development of new tuberculosis treatment methods, and we have formed alliances with various global companies with strengths in public health and operations in the areas where we do not have business operations (Mylan in India/South Africa and R-Pharm in Russia).

In March 2017, we launched a new delamanid clinical access program (DCAP) in cooperation with the South African government. The aim of the national program is to give patients with MDR-TB swift access to DELTYBA before regulatory approval. In other initiatives, Otsuka Pharmaceutical is working to establish sustainable drug delivery systems at affordable prices, so that patients around the world who need DELTYBA can be treated regardless of socioeconomic status or income level. As of June 2019, more than 80 countries are expanding use of DELTYBA based on this multifaceted approach.

### Interview

#### An indispensable company in global health

At our R&D institutes, we conduct unique research that does not imitate other companies and pursue what only Otsuka can do. DELTYBA is the embodiment of such efforts. Tuberculosis is a serious global health problem, and our approach to the problem—the belief that somebody must keep confronting the disease—has remained unchanged even now after more than 40 years since Otsuka initiated its research. Based on our corporate philosophy “Otsuka-people creating new products for better health worldwide,” we will continue working with external stakeholders to benefit global health with a sense of speed and commitment. Through these activities, we will continue to address issues that have not been solved globally. In the process, we believe, we will fulfill our aim of becoming an indispensable contributor to people’s health worldwide.



Keiso Yamasaki  
Otsuka Pharmaceutical Co., Ltd.  
Global Project Leader of TB Project

### Column

#### Next-generation tuberculosis drug candidate, OPC-167832

Otsuka Pharmaceutical is conducting research into tuberculosis drugs that will follow DELTYBA. The latest development is a compound called OPC-167832, which as of 2019 is undergoing initial trials in South Africa to confirm its safety and efficacy. OPC-167832 kills tuberculosis bacteria through a mechanism that inhibits the activity of enzymes that are essential for synthesizing mycobacterium tuberculosis cell walls. Because its mechanism of action differs completely from those of existing anti-tuberculosis drugs, including DELTYBA, it is expected to be effective as a treatment for various strains of TB. In developing the drug, we are also receiving support from the Bill & Melinda Gates Foundation, which has cited elimination of tuberculosis worldwide as one of its top priorities. We will continue engaging in TB R&D with the aim of establishing innovative treatment methods.



## Value Creation Section

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- 28 Seeking to provide value through business
- 30 Value Creation Model
- 32 Financial Highlights
- 34 Non-Financial Highlights

#### Hi-z Tower

The building pictured is part of the Tokushima Research Institute and named after the drug that laid the foundation of the Otsuka group’s pharmaceutical business. The ceramic mural on the wall was designed by Taro Okamoto and called *Inochi Odoru*, or “dancing life”, named by a notable Tokushima writer and activist Jakucho Setouchi. Other research centers of Otsuka Pharmaceutical are situated nearby.

# Growth Trajectory

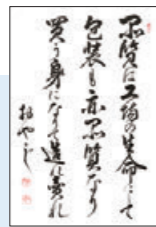
— From chemical raw materials to pharmaceuticals, beverages, and foods

Since the Otsuka group's founding in 1921 as a chemical raw material manufacturer, we have built on the IV solutions business that spurred the group's growth and continued to diversify our operations and achieve steady growth by bringing to market a series of original products such as *Oronine H Ointment*, *ORONAMIN C drink*, *Bon Curry*, *POCARI SWEAT*, and *Calorie Mate*, as well as pharmaceuticals such as the antipsychotic agent *ABILIFY*, a drug with a novel mechanism of action, and *Samsca*, the world's first oral aquaretic drug.

## Foundation phase

### Started business in Naruto, Tokushima Prefecture in Japan

The Otsuka group started out in 1921 as a manufacturer of chemical raw materials for the production of magnesium carbonate derived from bittern, the residue that remains in salt pans after salt production. This business made steady progress to supply a broader range of pharmacopeia raw materials and then in 1946 we entered the IV solutions business and expanded nationwide with the launch of our own intravenous drip solution.



"Quality is vital in a factory and so is packaging. We have to manufacture and market, putting ourselves in the consumer's position."

The Otsuka group's guiding precept in the founder's handwriting. It expresses a commitment to quality and still serves as the basis for Otsuka's manufacturing today.



Original IV solution. With over 70 years of experience in the intravenous solutions business, we are a leading company at the forefront of Japan's IV solutions industry.

## Growth phase

### Numerous unique products opened up new markets and diversified our business

During this period the group leveraged the technologies and know-how cultivated from the expansion of its IV solutions and clinical nutrition products businesses to successively spawn its unique core brands—the ion supply drink *POCARI SWEAT*, the balanced nutritional food *Calorie Mate*, and the world's first commercial retort pouch food product *Bon Curry*. In 1971 we started in-house pharmaceutical R&D and established the group's business foundation to deliver total healthcare solutions via the twin business segments of pharmaceuticals and nutraceuticals.



World's first commercially available product in a retort pouch, *Bon Curry*



Balanced nutritional food, *Calorie Mate*

## International business development phase

### Started aggressive global expansion

Drawing on the advanced technological know-how cultivated in Japan, we started to expand the IV solutions business to overseas markets in the 1970s. We currently have 15 business companies worldwide manufacturing and selling our products. We are committed to local manufacturing with the aim of maintaining and improving quality, which we think contributes to local communities mainly in the form of fair product pricing and employment creation. We also began to market *POCARI SWEAT* overseas in 1982, a product that is now sold in more than 20 countries and regions.



China Otsuka Pharmaceutical Co., Ltd. In 1981 Otsuka became the first Japanese pharmaceutical company to establish a joint venture in China.



Indonesian high school students enjoying *POCARI SWEAT*

(Billions of yen)

1,500

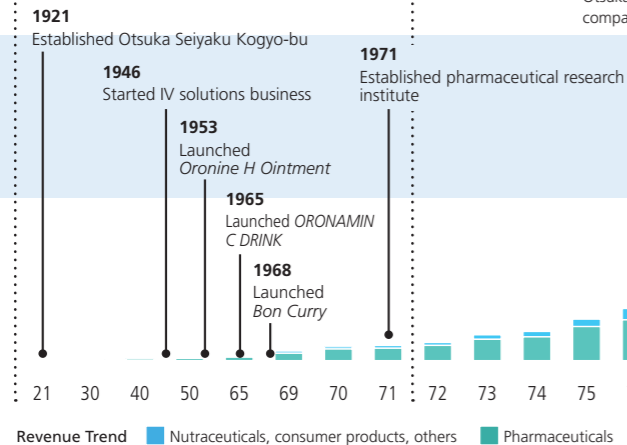
1,200

900

600

300

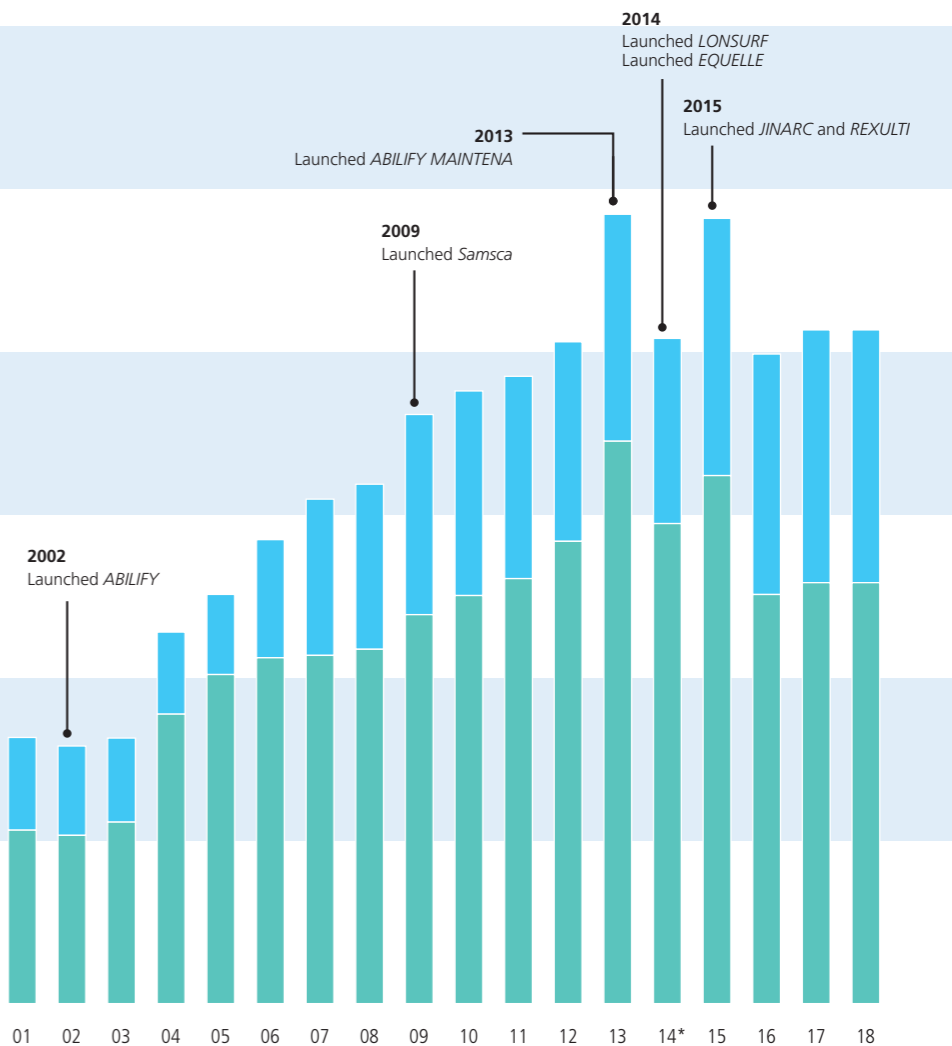
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## Expansion phase

### Seeking further global growth as a total healthcare company

In the pharmaceutical business, the antipsychotic agent *ABILIFY*—which first went on sale in the US in 2002—is now available through prescription in roughly 60 countries and regions and has greatly accelerated the Otsuka group's global expansion. Even today, the therapeutic drugs we have produced under our in-house drug discovery program are helping to treat diseases worldwide. These pharmaceuticals include the long-acting antipsychotic agent *ABILIFY MAINTENA*, the new antipsychotic agent *REXULTI*, the V<sub>2</sub>-receptor antagonist *Samsca/JINARC/JYNARQUE*, and the anti-cancer agent *LONSURF*. In the nutraceuticals business, our group companies are addressing health issues and needs in different corners of the world. For example, Pharmavite, which operates a nutritional supplements business mainly in the US, Nutrition & Santé, a nutritional food company in Europe, and Daiya Foods, which develops plant-based foods in North America.



\* 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.

## Seeking to provide value through business

The Otsuka group contributes to people's health worldwide by creating innovative products in two core businesses: the pharmaceutical business aims to address unmet medical needs, while the nutraceutical business seeks to fulfill yet-to-be imagined consumer needs.

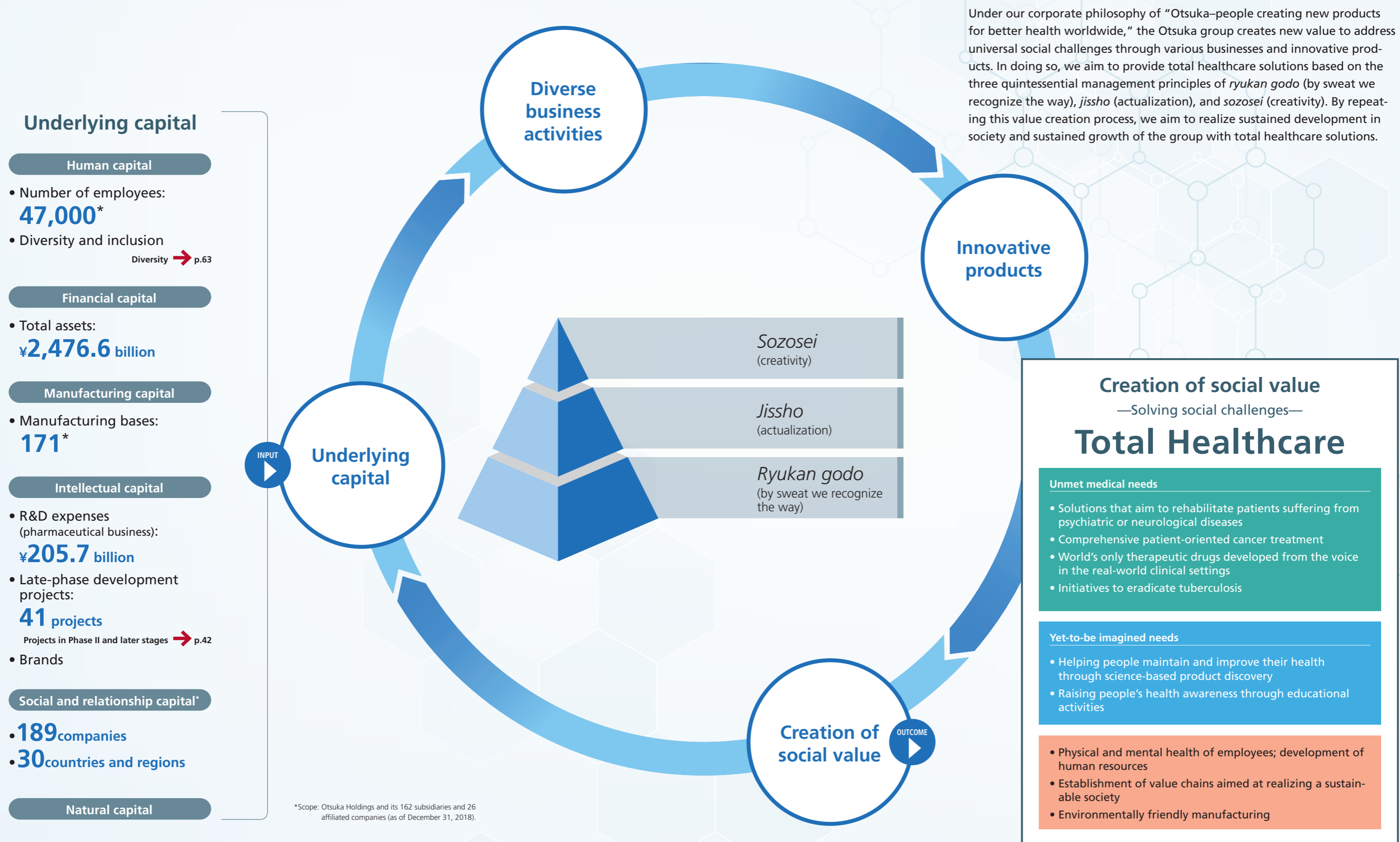
<The value we aim to provide>

# Total Healthcare





# Value Creation Model



Under our corporate philosophy of “Otsuka—people creating new products for better health worldwide,” the Otsuka group creates new value to address universal social challenges through various businesses and innovative products. In doing so, we aim to provide total healthcare solutions based on the three quintessential management principles of *ryukan godo* (by sweat we recognize the way), *jissho* (actualization), and *sozosei* (creativity). By repeating this value creation process, we aim to realize sustained development in society and sustained growth of the group with total healthcare solutions.

## Underlying capital

- Human capital**
  - Number of employees: **47,000\***
  - Diversity and inclusion Diversity → p.63
- Financial capital**
  - Total assets: **¥2,476.6 billion**
- Manufacturing capital**
  - Manufacturing bases: **171\***
- Intellectual capital**
  - R&D expenses (pharmaceutical business): **¥205.7 billion**
  - Late-phase development projects: **41 projects** Projects in Phase II and later stages → p.42
  - Brands
- Social and relationship capital\***
  - 189 companies**
  - 30 countries and regions**
- Natural capital**

\*Scope: Otsuka Holdings and its 162 subsidiaries and 26 affiliated companies (as of December 31, 2018).

### Creation of social value

—Solving social challenges—

## Total Healthcare

**Unmet medical needs**

- Solutions that aim to rehabilitate patients suffering from psychiatric or neurological diseases
- Comprehensive patient-oriented cancer treatment
- World’s only therapeutic drugs developed from the voice in the real-world clinical settings
- Initiatives to eradicate tuberculosis

**Yet-to-be imagined needs**

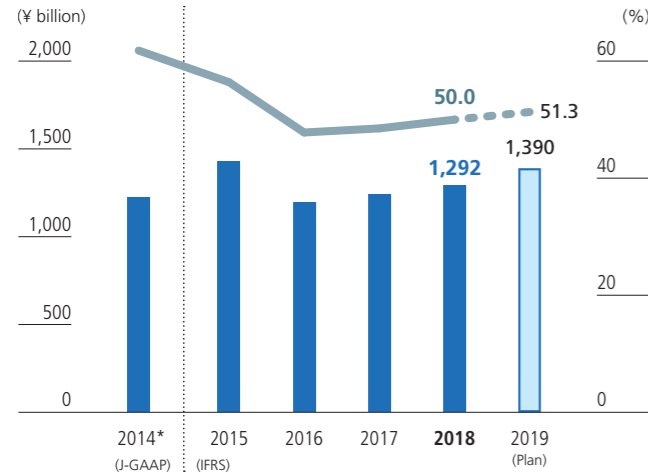
- Helping people maintain and improve their health through science-based product discovery
- Raising people’s health awareness through educational activities

- Physical and mental health of employees; development of human resources
- Establishment of value chains aimed at realizing a sustainable society
- Environmentally friendly manufacturing

# Financial Highlights

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

## Revenue

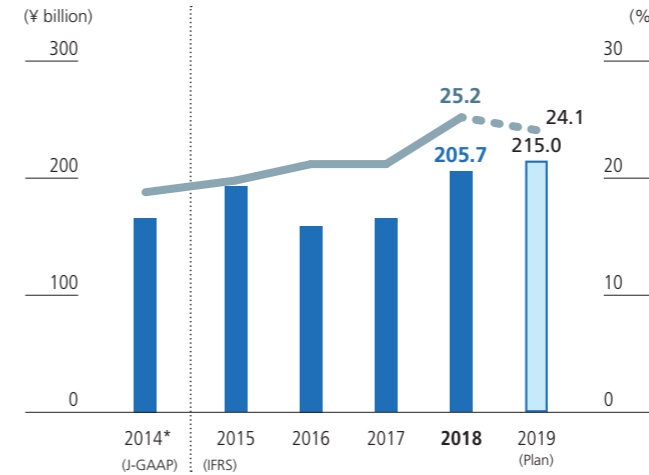


**Revenue**  
**¥ 1,292 billion** Up 4.2% YoY **Overseas sales ratio 50.0%**

Revenue grew 4.2% from the previous year, mainly due to growth in sales of our growth drivers in the pharmaceutical business, which are three global products (*ABILIFY MAINTENA*, *Samsca/JINARC/JYNARQUE*, and *REXULTI*) and new products in Japan. Growing sales volume of *POCARI SWEAT* in the nutraceutical business also contributed to our revenue growth.

■ Revenue  
 — Overseas sales ratio

## R&D expenses in pharmaceutical business

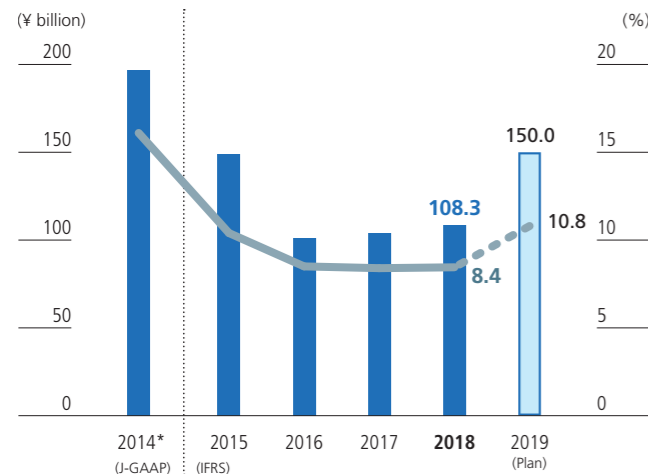


**R&D expenses in pharmaceutical business**  
**¥ 205.7 billion** Down 24.3% YoY **R&D expenses ratio in pharmaceutical business 25.2%**

R&D expenses in pharmaceutical business increased by 24.3% from the previous year, as a result of active R&D investments to maximize the value of our in-house developed products in the core therapeutic areas of psychiatry and neurology, oncology, and cardiovascular and renal system.

■ R&D expenses in pharmaceutical business  
 — R&D expenses ratio in pharmaceutical business

## Operating profit

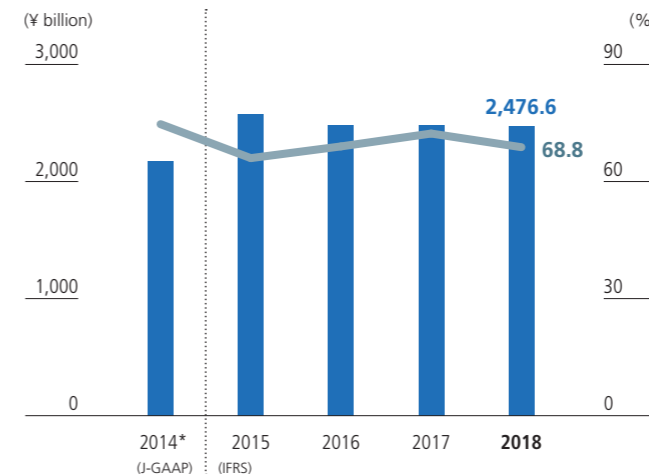


**Operating profit**  
**¥ 108.3 billion** Up 4.0% YoY **Operating profit margin 8.4%**

Operating profit increased by 4.0% from the previous year. In spite of increased R&D expenses and one-time expenses including an impairment loss, increased revenue in the pharmaceutical and nutraceutical businesses absorbed them.

■ Operating profit  
 — Operating profit margin

## Total assets

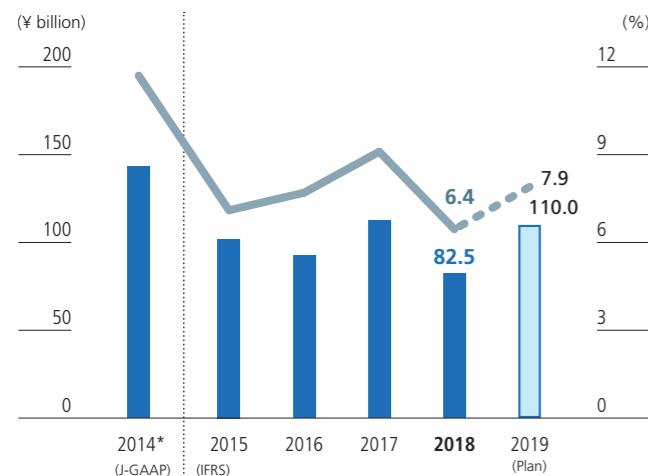


**Total assets**  
**¥ 2,476.6 billion** **Ratio of equity attributable to owners of the Company to total assets 68.8%**

Ratio of equity attributable to owners of the Company to total assets has been maintained at a high level. We are promoting active investment to enhance competitiveness and business growth as well as pursuing operational efficiency.

■ Total assets  
 — Ratio of equity attributable to owners of the Company to total assets

## Profit attributable to owners of the Company

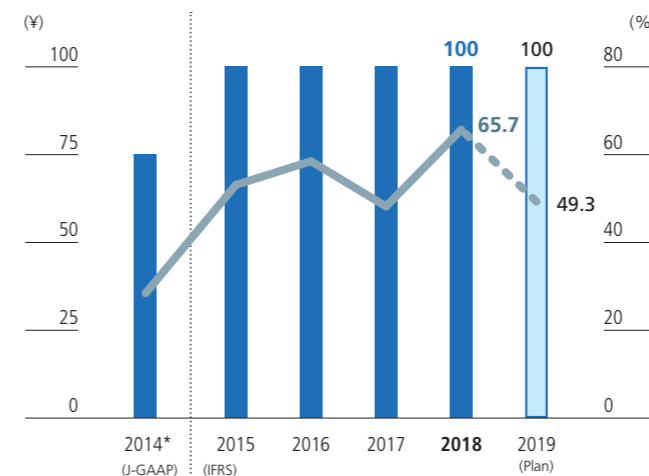


**Profit attributable to owners of the Company**  
**¥ 82.5 billion** Down 26.7% YoY **Ratio of profit attributable to owners of the Company 6.4%**

Profit attributable to owners of the Company decreased by 26.7% from the previous year since the US tax reform resulted in a large reduction of deferred tax liability in the previous year. Excluding the impact of the tax reform, this year's results were at almost the same level as the previous year.

■ Profit attributable to owners of the Company  
 — Ratio of profit attributable to owners of the Company

## Dividend per share



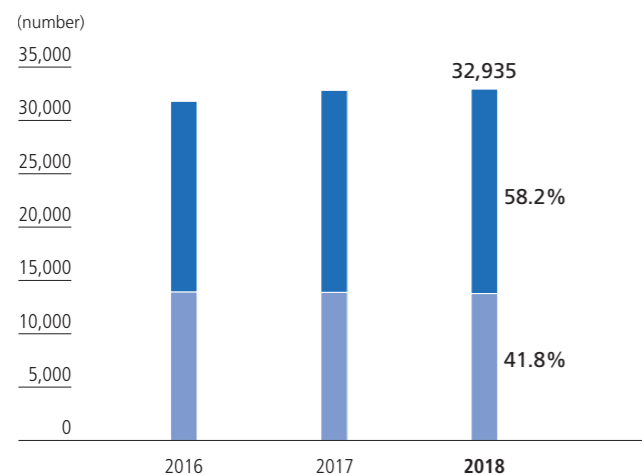
**Dividend per share**  
**¥ 100** **Dividend pay-out ratio 65.7%**

The Otsuka group considers profit distribution to shareholders is an important management issue. Our basic policy is that we maintain stable and continuous profit distribution while securing enough cash to invest for our business growth and prepare for changes in the business environment.

■ Dividend per share  
 — Dividend pay-out ratio

# Non-Financial Highlights

## Number of employees

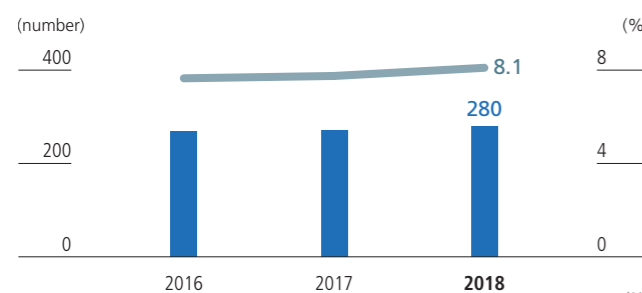


Number of employees **32,935**  
Ratio of employees outside Japan **58.2%**

The Otsuka group strives to utilize diverse human resources in order to adapt to the acceleration of the global business expansion and the varied social needs. Our employee ratio outside Japan increased from 52% in 2014 to approximately 58% in 2018.

■ Outside Japan ■ Japan  
\*Scope: Otsuka Holdings and its 162 subsidiaries

## Female manager ratio



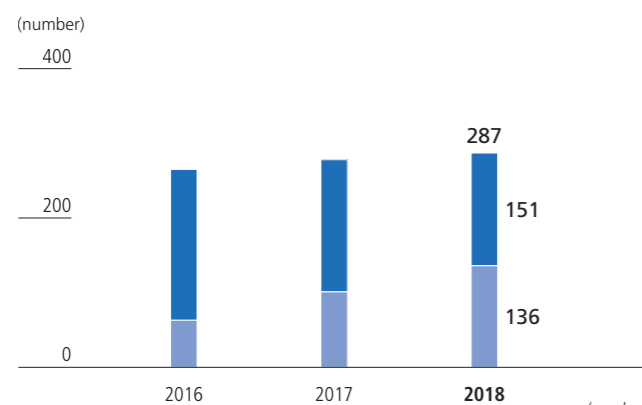
Female manager ratio **8.1%**

The Otsuka group believes that the active involvement of diverse human resources in a free and open workplace environment invokes creativity, which in turn leads to sustainable corporate growth. Accordingly, we actively promote diversity, including the active participation of female employees.

■ Number of female managers — Female manager ratio  
Scope: 6 companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, Otsuka Warehouse, and Otsuka Foods

	2016	2017	2018
Otsuka Pharmaceutical	9.0	9.3	9.5
Otsuka Pharmaceutical Factory	4.6	4.7	5.1
Taiho Pharmaceutical	6.2	6.3	6.6
Otsuka Chemical	8.6	9.2	9.4
Otsuka Warehouse	10.4	7.1	8.1
Otsuka Foods	7.0	7.3	7.4

## Number of employees acquiring childcare leave



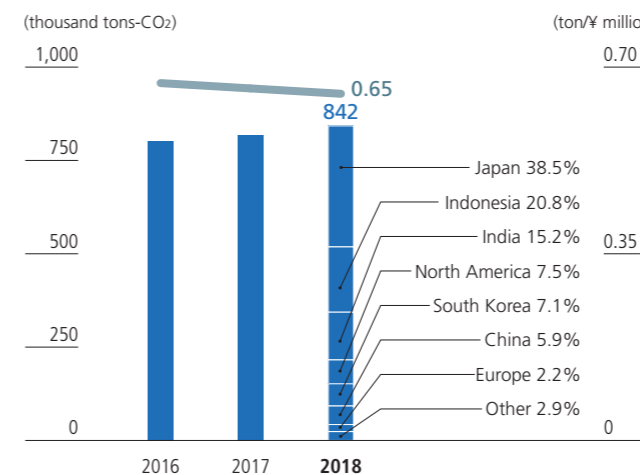
Number of employees acquiring childcare leave **287**

The Otsuka group supports employees in achieving a balance between childcare and work, through measures including the opening of three workplace nursery facilities, the holding of seminars on achieving a balance between childcare and work, and the enhancement of various related systems.

■ Female ■ Male  
Scope: 6 companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, Otsuka Warehouse, and Otsuka Foods

	2016	2017	2018
Female	202	177	151
Male	63	101	136

## Total CO2 emissions

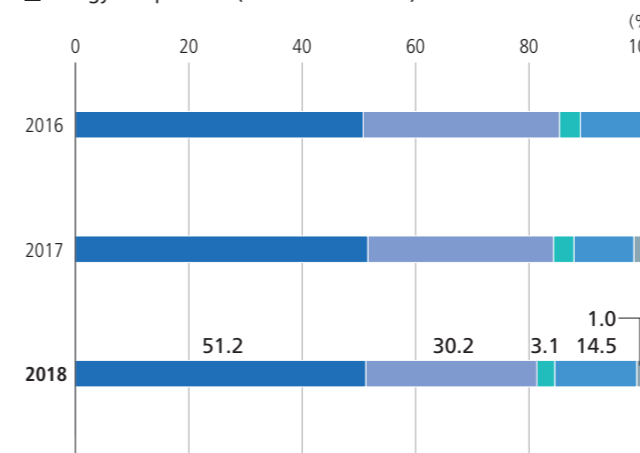


Total CO2 emissions **842 thousand tons-CO2**  
2030 Target: Reduce CO2 emissions by 30% compared to 2017

The Otsuka group is working to reduce our total CO2 emissions by making more efficient use of energy through the use of cogeneration systems and renewable energy. In fiscal 2018, total CO2 emissions increased from the previous year, due to an increase in production resulting from the acceleration of our global expansion.

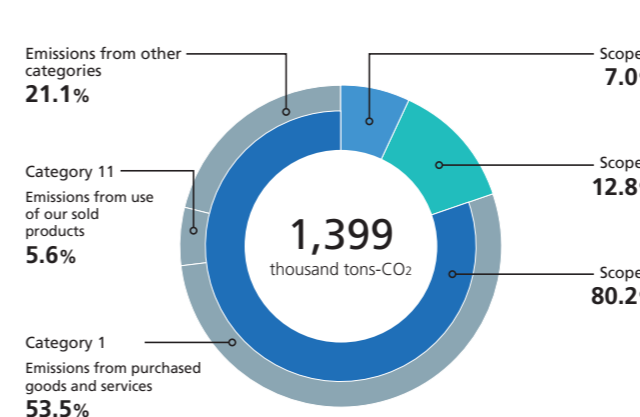
■ Total CO2 emissions — CO2 emissions per sales  
\*Scope: Calculated for the consolidated subsidiaries of the Otsuka group, and the companies that constitute the top 95% or more of CO2 emissions originating from energy.

## Energy composition (calorie conversion)



■ Purchased electric power ■ Natural gas ■ Heavy oil, etc. ■ Other (purchased steam, coal, etc.) ■ Renewable energy  
\*Scope: Calculated for the consolidated subsidiaries of the Otsuka group, and the companies that constitute the top 95% or more of CO2 emissions originating from energy.

## GHG emissions throughout the value chain in fiscal 2018

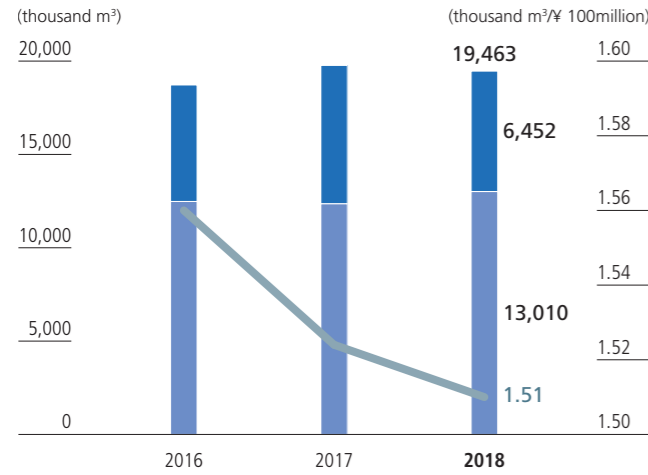


GHG emissions **1,399 thousand tons-CO2**

The Otsuka group assesses environmental impacts throughout the value chain for its five major companies in Japan with large environmental impacts. In addition to emissions due to corporate activities (Scopes 1, 2), we calculate the emissions stemming from the activities of suppliers, customers, and other parties (Scope 3). We will continue our efforts to calculate greenhouse gas (GHG) emissions, with the aim of further reducing our CO2 emissions throughout the value chain.

5 companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods

## Water usage and water use efficiency



### Water usage

**19,463** thousand m³

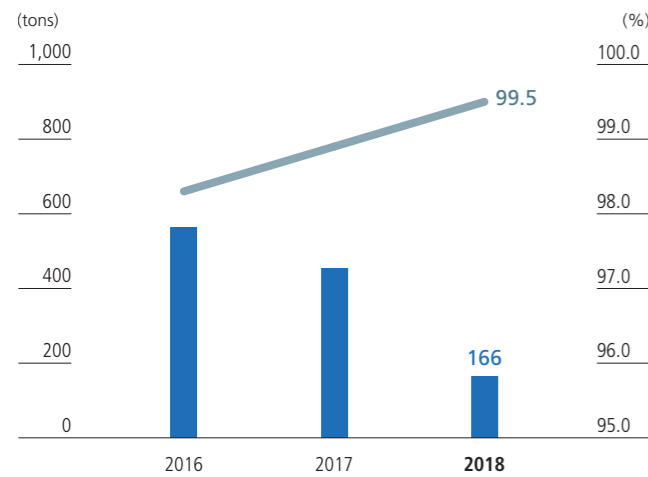
2030 Target:  
Improve water use efficiency  
by 15% compared to 2017

We assess the state of water risk and the amount of water used at our manufacturing sites around the world, as we work to achieve community-based management and the effective use of water resources in order to achieve a sustainable society.

■ Outside Japan ■ In Japan

\*Scope: Calculated for the consolidated subsidiaries of the Otsuka group, and the companies that constitute the top 95% or more of CO<sub>2</sub> emissions originating from energy.

## Resource recycling rate and final disposal amount



### Resource recycling rate

**99.5%**

The 14 Otsuka group companies in Japan have been promoting the recycling and reuse of resources and achieved a 99.5% recycling rate and zero emissions (based on our internal standard of a recycling rate of 99% or higher) in fiscal 2018.

We will continue striving for zero emissions and undertaking the 3Rs (Reduce, Reuse, and Recycle).

■ Final disposal amount ■ Resource recycling rate

\*Scope: 14 major consolidated subsidiaries in Japan

# Business Strategy Section

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### 10<sup>th</sup> Research Center (Tokushima Research Institute)

Pictured is the Otsuka group's drug discovery center building, which houses pharmacology and synthesis departments. It also provides a space where researchers from different disciplines can freely exchange information with each other and engage in discussion.

# Research and Development

## R&D Activities—Pharmaceutical Business

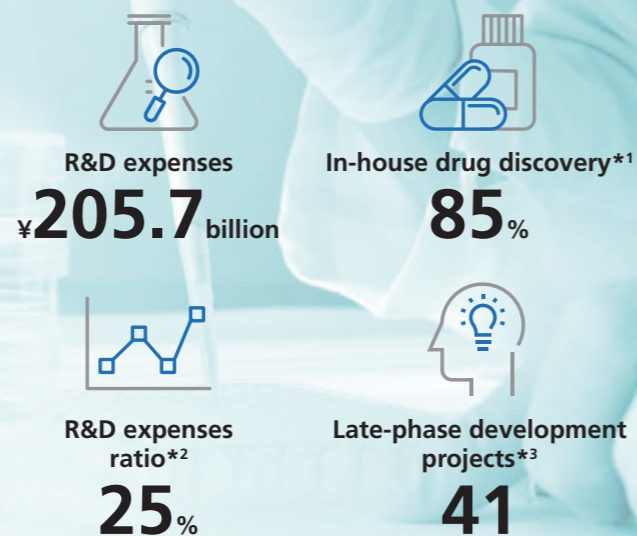
Powered by aggressive R&D investments, we aim to contribute to unmet medical needs by creating innovative products.

### R&D policy

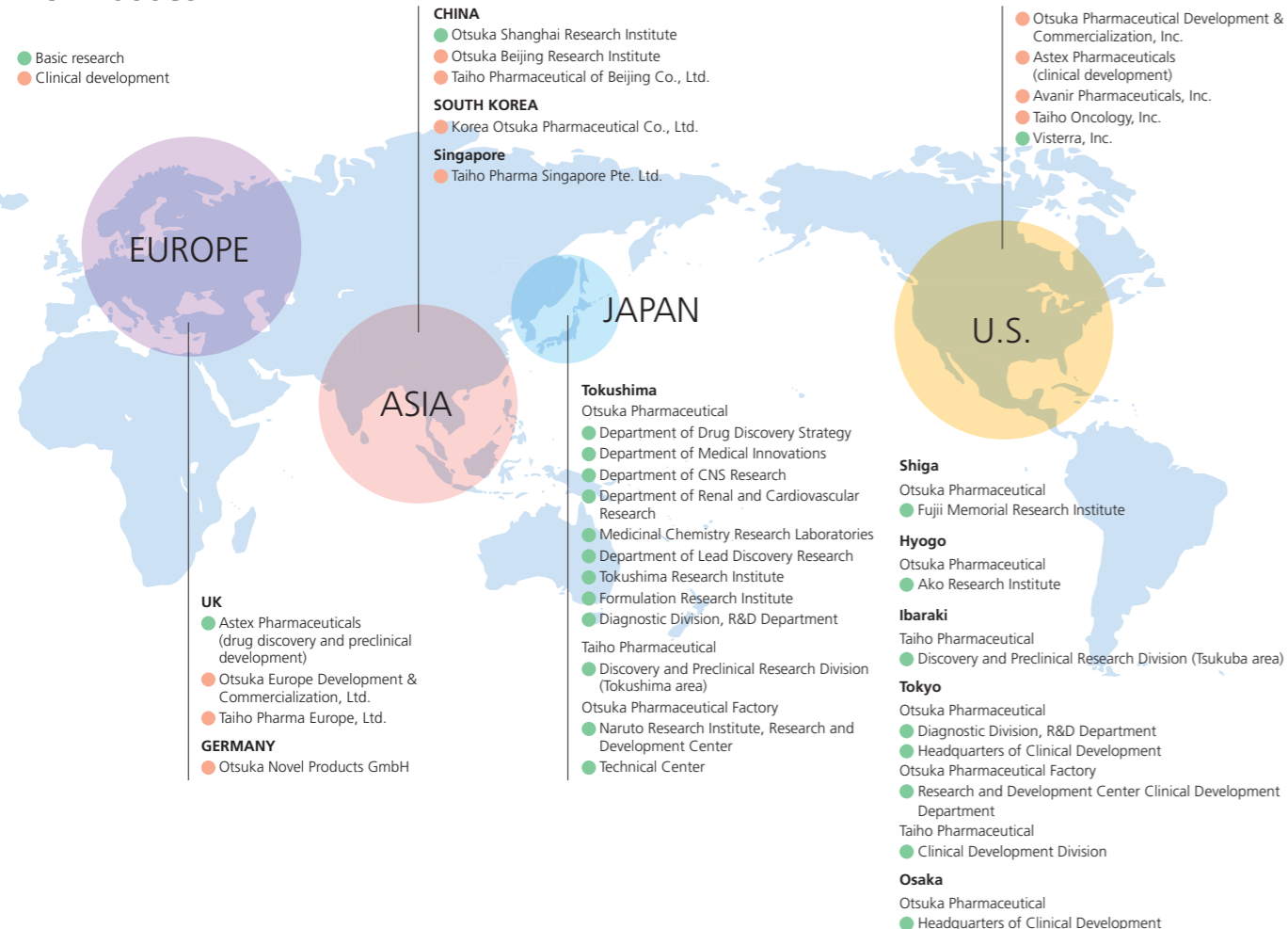
Driven by our corporate philosophy of “Otsuka—people creating new products for better health worldwide,” the Otsuka group aims to achieve highly innovative drug discovery to find solutions for unmet medical needs. With this goal in mind, we engage in multi-lateral R&D activities.

In addition to collaboration between group companies boasting expertise in numerous fields, we are working to bolster our in-house drug discovery platform, including human resources development, through access to innovative technologies and ideas involving research support and network-building with universities, research institutes, and bio-ventures that possess leading-edge research technology and drug discovery seeds.

\*1: Ratio of in-house drug discovery projects in late-phase development projects  
 \*2: R&D expenses in pharmaceutical business  
 \*3: Phase II or later stage of development as of December 31, 2018

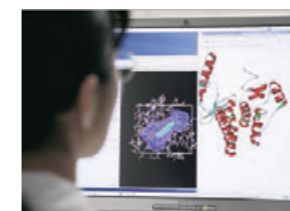


## R&D bases



## Proprietary drug discovery business model

—Generating new strengths and innovation through group cooperation—



The Otsuka group has built a solid foundation that continues to drive innovation ahead of its time through our own drug discovery research centering on Otsuka Pharmaceutical, which has R&D strengths in the areas of psychiatry and neurology, Taiho Pharmaceutical, which possesses its own drug discovery technology platform with a focus on oncology, and Otsuka Pharmaceutical Factory, a leading company in intravenous solutions. We have also welcomed into the group Astex Pharmaceuticals, a pioneer in fragment-based drug discovery, Avanir Pharmaceuticals, which boasts strengths in development in the field of neurological diseases, and Visterra, Inc. a company possessing unique antibody platform technology. By mutually sharing cutting-edge proprietary technology, inherent viewpoints, and the strong desire to challenge difficult-to-treat diseases, we are continuing to take our R&D to the next level to generate new strengths and innovation.



## Hierotope® platform —Visterra’s proprietary antibody platform technology—

Visterra possesses proprietary antibody platform technology—the *Hierotope*® platform. It enables the design of antibody drugs by targeting identified epitopes thought to be essential to protein function and simulating on a computer the binding of epitopes to the substructure of countless antibodies. *Hierotope*® refers to the region comprised of a robust three-dimensional structure of amino acids that is believed to play a critical role in the structure, function, and activity of protein. Using a combination of computational and experimental methods, this technology designs and engineers antibodies that strongly bind to *Hierotope*®. Unlike traditional approaches, this completely novel technology enables the design and development of antibodies for disease and drug discovery targets hitherto considered difficult. We thus aim to provide new therapeutic drugs for diseases where unmet medical needs still remain.



## Core Product Development

### Psychiatry & Neurology

#### [ brexpiprazole ]

Brexpiprazole is a new antipsychotic agent with a novel mechanism of action known as serotonin-dopamine activity modulator (SDAM)\*1. It is sold under the brand name *REXULTI* as an adjunctive therapy for major depressive disorders and as a schizophrenia treatment in the US. In Japan and Europe it is only used for schizophrenia treatment. Clinical trials are currently underway to utilize the properties of this agent in order to provide effective methods of treatment in other unmet fields, such as for agitation associated with dementia of the Alzheimer's type or post-traumatic stress disorder (PTSD).

It is estimated that approximately 10 million\*2 people in the G7 countries suffer from Alzheimer's and many of those patients are said to exhibit some form of behavioral disorder such as excessive motor activity, verbal aggression, or physical aggression. These symptoms have an impact on not just the patient—they place a strain on family members and caregivers and significantly affect quality of life. PTSD is a mental disorder that develops as a result of exposure to a traumatic event or experiencing severe mental stress, including earthquakes and other natural disasters, fires, accidents, violence, or criminal damage. A person suffering from PTSD may be afflicted with trauma-driven fear and anxiety even after a long time has elapsed. The number of PTSD patients in the G7 countries is estimated to be around 20 million\*3.

\*1 Provides a combination of partial agonist activity at serotonin 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors, and antagonist activity at serotonin 5-HT<sub>2A</sub> receptors.  
 \*2 © 2019 Alzheimer's Disease - Epidemiology - Mature Markets Data, Total prevalent cases of AD, DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited.  
 \*3 © 2019 Post Traumatic Stress Disorder - Epidemiology - Mature Markets Data, Total 12-month prevalent cases - Full Detail, © DR/ Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited.

#### [ AVP-786 ]

AVP-786 is a new compound of deuterium-modified dextromethorphan and quinidine. The drug is currently being studied in Phase III trials as a candidate for moderate-to-severe agitation in patients with Alzheimer's dementia and has been granted a fast

track designation by the US Food and Drug Administration (FDA). Clinical trials of AVP-786 are also ongoing for other psychiatric and neurological disorders where many unmet medical needs exist, such as patients with negative symptoms of schizophrenia, traumatic brain injury, and intermittent explosive disorder.

#### [ centanafadine ]

Centanafadine has a triple reuptake inhibitor action mechanism that modulates norepinephrine, serotonin, and dopamine reuptake. It is currently undergoing Phase III trials in the US as a candidate for attention deficit hyperactivity disorder (ADHD) in adults. ADHD is a developmental disorder characterized by difficulty paying attention (easily distracted, forgetful), excessive activity, and impulsiveness (fidgeting, unable to sit still). It is estimated that in the US there are 12 million potential ADHD patients among adults and 8.2 million among children\*4. With no fundamental treatment method, stimulant drugs are usually prescribed, but they pose other problems, such as their effect on the central nervous system, mental dependency, and drug resistance, while abuse of stimulants is also seen as a problem. Accordingly, a safer drug with a lower risk of abuse that can achieve comparable efficacy to stimulant drugs is needed.

\*4 © 2019 Attention-Deficit-Hyperactivity Disorder - Epidemiology - Mature Markets Data, Total pediatric and adult ADHD prevalent cases - DSM-IV - Full Detail, DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited.

#### [ fremanezumab ]

Fremanezumab is an anti-calcitonin gene-related peptide (CGRP) monoclonal antibody for the prevention of migraines. It is administered monthly as a subcutaneous injection. It is expected to prevent migraines by selectively binding to CGRP, thought to be a key factor in the cause of migraines, thus inhibiting CGRP binding to its receptor. The Otsuka group has concluded an exclusive license agreement with Teva Pharmaceutical Industries for the development and commercialization in Japan. The drug is currently undergoing Phase III trials in Japan as a candidate for the prevention of episodic and chronic migraines.

#### [ ASTX727 ]

ASTX727 is the world's first oral DNA methylation inhibitor combination drug containing the DNA methylation inhibitor decitabine and metabolic enzyme (cytidine deaminase) inhibitor cedazuridine. The administration of currently approved methylation inhibitors requires patients to visit hospital for an intravenous injection, but the orally administered ASTX727 has the potential to become a new treatment option that alleviates this burden on MDS patients. Having met primary endpoints in Phase III trials for the treatment of MDS, we are aiming to submit an application for approval before the end of 2019.

#### [ TAS-116 ]

TAS-116 has the potential to exhibit anti-tumor effects by inhibiting heat shock protein 90 (HSP90) and destabilizing and reducing multiple proteins involved in cancer growth and survival. HSP90 is known to be particularly important in the survival and maintenance of cancer cells because it is expressed highly in cancer cells and tumor tissue and exists in a highly activated state. A Phase III

trial is ongoing for this drug as a candidate for treating gastrointestinal stromal tumor (GIST), one of the rarer forms of cancer in Japan. GIST is a malignant type of tumor that occurs in the wall of the gastrointestinal tract and many patients often experience a recurrence or metastasis. The incidence rate in Japan is around 1–2 per 100,000 people.

### Cardiovascular & Renal

#### [ vadadustat ]

Vadadustat is an oral therapeutic drug currently subject to Phase III trials as a candidate for the treatment of anemia associated with chronic kidney disease in non-dialysis and dialysis patients. It works to stabilize and modulate the hypoxia-inducible factor (HIF), the transcription factor that activates erythropoietin, by inhibiting HIF prolyl hydroxylase (HIF-PH), the enzyme that breaks down HIF. HIF responds to changes in oxygen concentration and controls gene expression involved in the production of red blood cells. HIF also acts to improve iron mobilization and by coordinating interdependent processes, it boosts red blood cell production and, ultimately, oxygen delivery. Under an agreement with Akebia Therapeutics, the Otsuka group has acquired the rights to joint development and marketing of vadadustat in the US, joint development and exclusive marketing in Europe, and exclusive development and marketing in Canada, Australia, China, and other countries\*, but excluding Central and South America.

\*Countries outside of Japan and Asia (Taiwan, South Korea, Singapore, Malaysia, Indonesia, etc.), where Mitsubishi Tanabe Pharma has acquired a license for the drug.

#### [ Ultrasound renal denervation treatment device ]

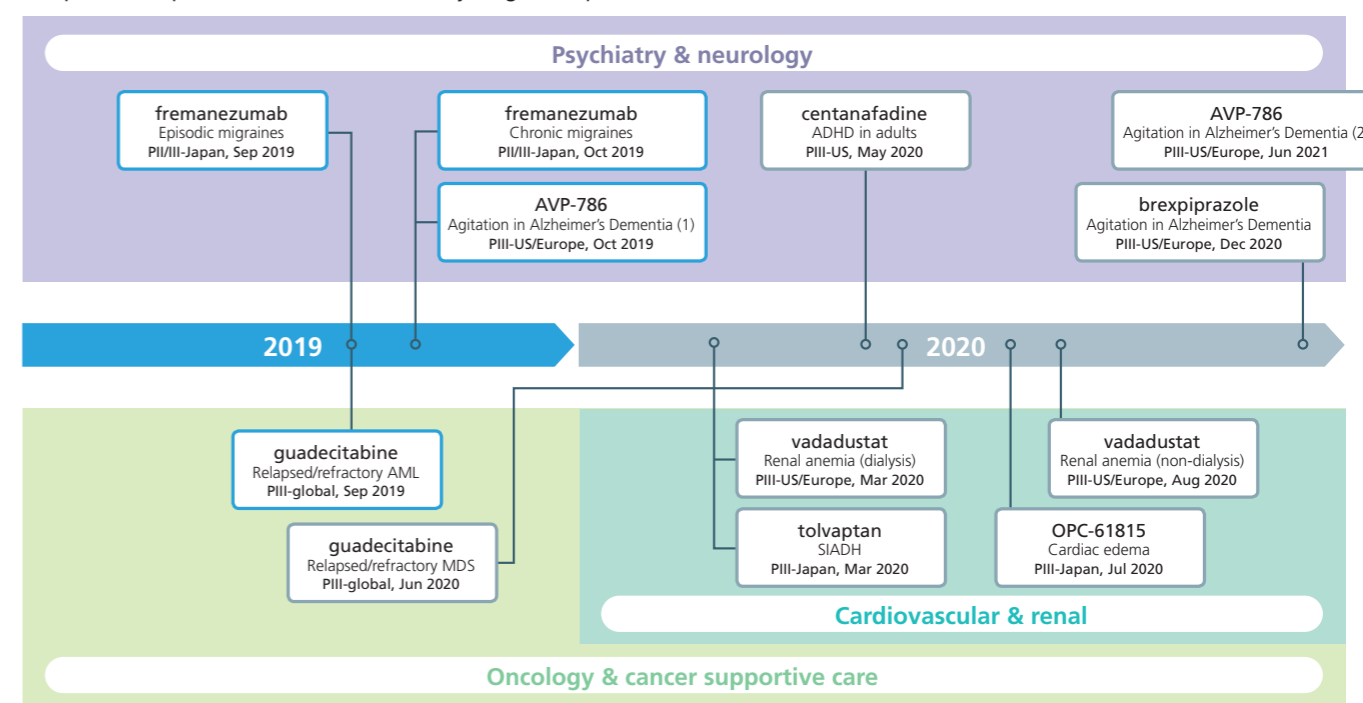
Renal denervation system is a new treatment method that has the potential to effectively lower blood pressure in patients with hypertension for whom existing hypotensive drugs are unable to do so. This technology downregulates hyperactivity of the renal sympathetic nerves by using a catheter-based system to percutaneously deliver ablations to the sympathetic nerves surrounding the renal arteries with heat generated from radio or ultrasound waves. The renal denervation device being developed by US-based Otsuka group company ReCor Medical utilizes a minimally invasive procedure on blood vessel walls to efficiently achieve nerve ablation effects. The system is characterized by delivering ablations concentrically to the renal sympathetic nerves using ultrasound energy while the artery wall is kept cool by circulating water within the artery. Trials are currently underway in the US to investigate the treatment of hypertension, and in Japan and South Korea to examine the potential for treating refractory hypertension.

### Oncology & Cancer Supportive Care

#### [ guadecitabine ]

Guadecitabine is a next-generation, low-molecular-weight DNA methylation inhibitor that is designed to allow the active metabolite decitabine to work longer in the body and thereby efficiently reach tissues such as the bone marrow. It is currently in Phase III trials for two indications: Relapsed/refractory acute myeloid leukemia (AML) in adults and Relapsed/refractory myelodysplastic syndromes (MDS) in adults.

Expected completion of Phase III trials for key drug developments (as of the end of June 2019)



## Projects in Phase II and later stages (as of March 31, 2019)

### Psychiatry & Neurology

Code (Generic name) <Brand name> Features	Origin	Indication	Country/ Region	Development status			
				Phase II	Phase III	Filed	Approved
OPC-34712 (brexpiprazole) <REXULTI> Dopamine partial agonist	Otsuka Pharmaceutical	Major depressive disorder	JP, EU, CN	█	█		
		Agitation associated with dementia of the Alzheimer's type	JP, US, EU	█	█		
		Bipolar I disorder	US, EU	█	█		
		Posttraumatic stress disorder	US, EU	█	█		
OPC-64005 Serotonin, norepinephrine and dopamine reuptake inhibitor	Otsuka Pharmaceutical	Attention deficit hyperactivity disorder	US	█	█		
TAS-205 PGD synthase inhibitor	Taiho Pharmaceutical	Duchenne muscular dystrophy	JP	█	█		
AVP-786 (deuterium-modified dextromethorphan, quinidine) NMDA receptor antagonist/Serotonin and norepinephrine reuptake inhibitor/Sigma-1 receptor agonist	Avanir	Agitation associated with dementia of the Alzheimer's type	US, EU	█	█		
		Negative symptoms of schizophrenia	US	█	█	*1	
		Traumatic brain injury	US	█	█		
		Intermittent explosive disorder	US	█	█		
EB-1020 (centanafadine) Norepinephrine, dopamine and serotonin reuptake inhibitor	Neurovance	Attention deficit hyperactivity disorder	US	█	█		
Lu AA36143 (nalmefene) <Selincro> Opioid receptor antagonist	Lundbeck	Alcohol dependence	JP	█	█		
TEV-48125 (fremanezumab) Anti-CGRP antibody	Teva	Migraine	JP	█	█	*1	

### Oncology

Code (Generic name) <Brand name> Features	Origin	Indication	Country/ Region	Development status			
				Phase II	Phase III	Filed	Approved
TAS-102 (trifluridine, tipiracil) <LONSURF> Interference with the function of DNA	Taiho Pharmaceutical	Colorectal cancer	CN	█	█		
		Gastric cancer	US	█	█		
			JP, EU	█	█		
TAS-118 (tegafur, gimeracil, oteracil, folinate) Anti-metabolite	Taiho Pharmaceutical	Gastric cancer	JP	█	█		
TAS-114 dUTPase inhibitor	Taiho Pharmaceutical	Non-small cell lung cancer	JP, US, EU	█	█		
TAS-115 Multi-kinase inhibitor	Taiho Pharmaceutical	Prostate cancer	JP	█	█		
TAS-116 HSP90 inhibitor	Taiho Pharmaceutical	Gastrointestinal stromal tumor	JP	█	█		
TAS-120 FGFR inhibitor	Taiho Pharmaceutical	Cholangiocarcinoma	JP, US, EU	█	█		
TAS0313 Peptide vaccine	Taiho Pharmaceutical	Urothelial cancer	JP	█	█		
TAS0728	Taiho Pharmaceutical	Solid tumors	US, EU	█	█	*2	
		Ovarian cancer	US, EU	█	█		
SGI-110 (guadecitabine) DNA methyltransferase inhibitor	Astex	Acute myeloid leukemia	JP, US, EU	█	█		
		Myelodysplastic syndrome	JP, US, EU	█	█		
ASTX727 DNA methyltransferase inhibitor	Astex	Myelodysplastic syndrome	US	█	█		
ASTX660 IAP inhibitor	Astex	Solid tumors, Lymphomas	US	█	█		
TBI-1301 NY-ESO-1 siTCR <sup>®</sup> gene therapies	Takara Bio	Synovial sarcoma	JP	█	█	*2	
TBI-1401 (canerpatrev) Oncolytic Virus	Takara Bio	Melanom	JP	█	█	*3	
TBI-1501 CD19 CAR gene therapies	Takara Bio	Acute lymphoblastic leukemia	JP	█	█	*2	
Pro-NETU (fosnetupitant) NK1 receptor antagonist	Helsinn Healthcare	Chemotherapy-induced nausea and vomiting	JP	█	█		

### Cardiovascular & Renal

Code (Generic name) <Brand name> Features	Origin	Indication	Country/ Region	Development status			
				Phase II	Phase III	Filed	Approved
OPC-41061 (tolvaptan) <Samsca> V2 receptor antagonist	Otsuka Pharmaceutical	Syndrome of inappropriate antidiuretic hormone secretion	JP	█	█		
OPC-61815 V2 receptor antagonist	Otsuka Pharmaceutical	Cardiac edema	JP	█	█		
AKB-6548 (vadadustat) HIF-prolyl hydroxylase inhibitor	Akebia	Anemia associated with chronic kidney disease	US, EU	█	█		

### Other areas

Code (Generic name) <Brand name> Features	Origin	Indication	Country/ Region	Development status			
				Phase II	Phase III	Filed	Approved
OPC-67683 (delamanid) <Delyba> Mycolic acid biosynthesis inhibitor	Otsuka Pharmaceutical	Multidrug-resistant tuberculosis	US	█	█		
OPC-167832 DPrE1 inhibitor	Otsuka Pharmaceutical	Tuberculosis	US	█	█	*2	
OPA-15406 PDE4 inhibitor	Otsuka Pharmaceutical	Atopic dermatitis	JP	█	█		
OPS-2071 New quinolone based antibacterial agent	Otsuka Pharmaceutical	Clostridium difficile infection, enteric infection	JP	█	█		
TAS-303 Selective norepinephrine reuptake inhibitors	Taiho Pharmaceutical	Stress urinary incontinence	JP	█	█		
TAS-115 Multi-kinase inhibitor	Taiho Pharmaceutical	Idiopathic Pulmonary Fibrosis	JP	█	█		
TAS5315 BTK inhibitor	Taiho Pharmaceutical	Rheumatoid arthritis	JP	█	█		
OPF-105 (Glucose, electrolyte, amino acid, fat and vitamin)	Otsuka Pharmaceutical Factory	Peripheral parenteral nutrition solution	JP	█	█		
VIS410 Anti-hemagglutinin monoclonal antibody	Visterra	Influenza A infection	US	█	█		
TAC-302	Meiji	Detrusor underactivity with overactive bladder	JP	█	█		

### Diagnostics

Code (Generic name) <Brand name> Features	Origin	Indication	Country/ Region	Development status			
				Phase II	Phase III	Filed	Approved
C13-CAC 13C-calcium carbonate breath test	Otsuka Pharmaceutical	Measurement of gastric acidity	JP	█	█		
ODK-1003-CN WT1 mRNA RT-PCR assay kit	Otsuka Pharmaceutical	Diagnosis for Myelodysplastic syndrome	CN	█	█		

\*1 Phase II/III  
\*2 Phase I/II  
\*3 Application by Takara Bio Inc.

# Pharmaceutical Business

## Social Challenges/Strengths/Overview

Providing total healthcare solutions, from disease diagnosis to treatment.



### Social challenges

In line with the evolution of life sciences, a number of new drugs are discovered every year. However, there are still many diseases that lack effective treatment methods or diseases for which existing treatment and drugs are unsatisfactory. Addressing the desire of all people to remain healthy is a universal and pressing issue.

In the pharmaceutical business, we have consistently embraced the challenge of solving issues from the standpoints of patients and medical professionals alike for roughly 50 years mainly in the fields of psychiatry and neurology, as well as oncology, where many unmet needs still exist.



### Otsuka's strengths

#### 1 A corporate culture that generates innovation

Each and every Otsuka group employee has a high regard for *jishho* (actualization) and *sozosei* (creativity)—the DNA of our corporate culture—and pursues innovation on a daily basis by always questioning common practice, from R&D departments to on-site operations.

#### 2 Providing total healthcare solutions, from diagnosis to treatment of disease

We employ a holistic approach to people's health and conduct business in a wide array of fields, including pharmaceuticals, clinical nutrition, diagnostic agents, and medical devices in order to provide comprehensive healthcare solutions, from diagnosis to treatment of disease.

#### 3 Long-held knowledge in core therapeutic areas

Since commencing R&D in the fields of psychiatry, neurology, and oncology in the 1970s, we continue to take steps to address unmet medical needs and spawn innovation in various forms.

### Fiscal 2018 business overview and mainstay products

In fiscal 2018, both revenue and profit were boosted by higher sales revenue for new products in Japan and overseas, despite the impact of drug price revisions in Japan, lower sales revenue from long-listed drugs owing to campaigns promoting the use of generics, and higher R&D costs associated with progress made on late-phase development products. Sales revenue came to ¥817.1 billion (+5.5% YoY) and operating profit to ¥84.8 billion (+2.6%).



**Antipsychotic Long-acting injectable**  
Generic name: aripiprazole Origin: Otsuka Pharmaceutical

ABILIFY MAINTENA is the once-monthly long-acting injectable of the antipsychotic agent ABILIFY discovered by Otsuka Pharmaceutical and commercialized under a global alliance with Lundbeck. The drug treats schizophrenia in adult patients and first launched in the US and Europe in 2013 and in Japan in 2015. It is currently sold in more than 35 countries. Sales revenue in fiscal 2018 increased 24% year on year to ¥88 billion, mainly reflecting a greater awareness of the efficacy for this indication and convenient formulation, as well as an increase in prescriptions following the July 2017 addition of maintenance treatment of bipolar I disorder in adults as an approved indication in the US.



**Antipsychotic**  
Generic name: brexpiprazole Origin: Otsuka Pharmaceutical

Through our global alliance with Lundbeck, our novel atypical antipsychotic agent REXULTI was approved in the US in 2015 as an adjunctive therapy for major depressive disorder and as a therapeutic drug for schizophrenia. In Japan and Europe it was approved in 2018 as a therapeutic drug for schizophrenia. The drug's high efficacy and safety based on its novel mechanism of action has been rated favorably by physicians and patients alike, which helped boost fiscal 2018 sales revenue by 46.9% year on year to ¥69.5 billion.



**V2-receptor antagonist**  
Generic name: tolvaptan Origin: Otsuka Pharmaceutical

Samsca/JINARC/JYNARQUE has been sold globally since 2009 as an oral aquaretic drug (brand name: Samsca) with a novel mechanism of action that excretes only water from the body with no direct impact on electrolyte excretion by inhibiting the antidiuretic hormone vasopressin. In 2014 it was approved as the world's first therapeutic drug for autosomal dominant polycystic kidney disease (ADPKD) under the brand name Samsca/JINARC/JYNARQUE, and has now been

approved for use in more than 40 countries. Prescriptions for the drug as an oral aquaretic continued to increase in fiscal 2018, mainly reflecting strong recommendations in various guidelines in Japan as a treatment for hepatic edema and cardiac edema. Prescriptions as a treatment for ADPKD also continue to grow on the back of more approved sales markets in Europe. Sales also commenced in the US in May 2018. Sales revenue rose 26.7% year on year to ¥75.9 billion for Samsca and grew a sharp 234.2% year on year to ¥14.3 billion for JINARC/JYNARQUE.



## Overview of therapeutic areas

# Psychiatry & Neurology

The fields of psychiatry and neurology are key areas of focus for Otsuka given the many diseases the causes of which are yet to be discovered and the difficulties involved in drug discovery R&D. We continue to embrace the challenge of providing trailblazing solutions that aim to rehabilitate patients back into society after suffering psychiatric or neurological disorders.

### Aiming to provide systematic solutions to address challenges in psychiatric and neurological healthcare

Psychiatric disorders such as schizophrenia, bipolar, and major depressive disorder cause problems for a person's social life, career, or studies because they can develop at any time from childhood through to late middle age. Moreover, concerns are growing about the increase in Alzheimer's as populations worldwide continue to age. These diseases affect not just the patient's quality of life; they place a strain on family and caregivers and create a burden for the healthcare economy. There are still many illnesses for which satisfactory treatments have yet to be established because their causes and mechanisms are not fully understood, which makes the discovery of new drugs extremely difficult.

The Otsuka group started conducting research and development in the fields of psychiatry and neurology in the 1970s and to this day we continue to work tirelessly on new drug development with the goal of contributing to medical needs in these disciplines.

The results of our research over a quarter of a century came to a head with the development of *ABILIFY*, the world's first dopamine partial agonist. It is evaluated highly in clinical settings for its efficacy and safety based on its novel pharmacological action and has

been prescribed to patients in more than 60 countries and regions worldwide. Harnessing our R&D experience with *ABILIFY* and drawing on feedback from professionals engaged in clinical practice, we developed *REXULTI*, a new drug with a completely novel mechanism of action. With *REXULTI*, we are advancing our research to address yet unmet major therapeutic needs left untreated worldwide—for example, schizophrenia, major depressive disorder, PTSD, and agitation associated with Alzheimer's disease.

And by developing and bringing to market long-acting injectables like *ABILIFY MAINTENA* to address the issue of medication adherence, trialing the use of *Abilify MyCite*, the world's first digital medicine system for patients to record their tablet ingestion, and developing digital therapeutic applications for treating major depressive disorder, we continue to focus on the unmet needs of patients with the aim of providing systematic solutions that address challenges in psychiatric and neurological healthcare with a unique approach of fusing together different technologies.

Core product development → p.40

### Unmet medical needs in psychiatry and neurology

#### Schizophrenia

Schizophrenia is a psychiatric disorder in which thoughts and emotions continue to be disordered. Appearing between adolescence and the age of maturity, it presents symptoms such as hallucinations, delusions, thought disorders, emotional flattening, and lack of motivation that can make employment and living in society difficult. Even today, with the advance of science, the causes of the disease have not been fully elucidated, and there is a need for long-term therapy and support aimed at a return to society, while ameliorating symptoms. Another issue is that a lack of recognition of the disease, and reduced medication adherence due to side effects, can lead to relapse in patients.

There are estimated to be 1.8 million patients in the US, 0.8 million in Japan, and 1.9 million in the five major countries of Europe.

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Misunderstandings and prejudices regarding psychiatric and neurological disorders still exist in society because they are not fully understood. Otsuka Pharmaceutical is confronting these issues head on by carrying out numerous activities aimed at educating people about these diseases.

<https://www.otsuka.co.jp/en/knowproject/>



# Oncology & Cancer Supportive Care

We are expanding our business in the fields of oncology and cancer supportive care with the aim of providing patient-oriented total care. And through collaboration between group companies and access to cutting-edge knowledge and innovative technology, we seek to achieve an even higher level of drug discovery.

### Sparking new innovation by melding proprietary technologies

With the launch of the tegafur-based oral formulation *Futraful* in Japan in 1974, Taiho Pharmaceutical pioneered the market for oral anti-cancer agents at a time when their use was still very uncommon. In its half century of anti-cancer drug research since then, the company has generated a large body of evidence and contributed to the establishment of cancer chemotherapy in Japan primarily with *TS-1* (combination drug of tegafur, gimeracil, and oteracil potassium), which has become the standard treatment for unresectable advanced or recurrent gastric cancer and the standard postoperative adjuvant chemotherapy for gastric cancer. And with the development and commercialization of the anti-cancer agent *LONSURF* in 2014, the subsequent establishment of a sales framework in North America, and a development and sales alliance with France-based Servier, Taiho Pharmaceutical continues to take up the challenge of expanding its global presence and value creation.

Astex Pharmaceuticals, which became part of the Otsuka group in 2014, is contributing to the commercialization of

numerous compounds owing to its proprietary fragment-based drug discovery. In addition to the DNA methylation inhibitors guadecitabine and *ASTX727*, successor drugs it developed by leveraging its knowledge of Dacogen (generic name: decitabine), a treatment for myelodysplastic syndromes and acute myeloid leukemia, the company currently has other promising drugs undergoing clinical trials.

Cancer therapy systems are currently changing rapidly as a result of advancements in science and technology. We are developing and expanding our drug discovery platform technology by harnessing the respective strengths of each group company and also stepping up the pace of research and development through collaborations and alliances. Through tie-ups with corporations and academia, including open innovation initiatives, we seek to promote access to cutting-edge knowledge and innovative technology and achieve an even higher level of drug discovery.

Core product development → p.40

### Unmet needs in oncology

#### Gastric cancer

Gastric cancer is the fifth most common type of cancer in the world and it is the third most common cause of cancer death, following lung and colorectal cancer. It is estimated that approximately 723,000 people die of gastric cancer every year\*<sup>1</sup>. In Japan it is the most common form of cancer and responsible for roughly 45,000 deaths annually, surpassed only by lung and colon cancer\*<sup>2</sup>.

Remarkable progress has been made in recent years on successfully treating gastric cancer and the survival period has dramatically increased in the past 10 years. That said, intensive chemotherapy cannot be used for treatment once the cancer progresses because of the many complications that arise, while the drugs that can be used are also limited. Extending the survival period and alleviating symptoms during late-stage treatment of metastatic gastric cancer are challenges for which new treatment options are certainly needed.

\*<sup>1</sup> Ferlay J, Soerjomataram I, Dikshit R, et al. *Int J Cancer*. 2015;136:E359-86.  
\*<sup>2</sup> Latest Cancer Statistics, a cancer information service of the National Cancer Center Japan (in Japanese)



In collaboration with the Shizuoka Cancer Center, Taiho Pharmaceutical provides information to help improve the lives of cancer patients. By doing so, it offers support to people who have experienced cancer to overcome the challenges they face in their daily life together with family, healthcare professionals, and other cancer survivors.

# Cardiovascular & Renal

## One more core therapeutic area in addition to psychiatry & neurology, oncology

Since our first in-house developed pharmaceutical, the hypotensive drug *Mikelan*, launched in 1980, we have continued to contribute to the treatment of cardiovascular diseases thanks to our groundbreaking novel drug discovery. Notably, the antiplatelet agent *Pletaal* and the world's first oral aquaretic drug *Samsca*. We are also establishing new assets overseas, for example, through our efforts to develop the world's first therapeutic drug for ADPKD. In seeking to make sustained contributions to the unmet needs of patients in the cardiovascular and renal fields, we intend to strengthen our in-house drug development and also make

aggressive growth investments, as illustrated by our vadadustat business alliance with Akebia Therapeutics and the acquisition of Visterra, a company with a product pipeline in the renal domain.

We also strive to find solutions to unmet needs in non-pharmaceutical areas too. We are propelling the development of unique medical devices that fuse innovative technology with our strengths in drugs and clinical research. Examples of this initiative include an ultrasound renal denervation treatment device and a peripheral artery stent.

Core product development → p.41

# Other Areas

## Providing total healthcare

### Clinical nutrition (intravenous solutions)

■ Fiscal 2018 sales revenue

¥ **111.1** billion

With more than 70 years of experience in the clinical nutrition business, the Otsuka group continues to contribute to a large number of patients as a leading company in Japan in the area of intravenous solutions. We made our first foray into overseas markets in the 1970s and our clinical nutrition business operations are now spread across 15 companies worldwide. This business continues to grow, centering on our basic solution business. Going forward, we will continue to develop high value-added products to meet market needs around the world and contribute to global healthcare.



Otsuka group's market share of intravenous solutions in Japan (2018)

**55.8%**

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### Diagnostic agents

■ Fiscal 2018 sales revenue

¥ **13.7** billion

Companion diagnostics\* play a key role in identifying the individual differences in the effects of drugs and their side effects so that appropriate healthcare can be provided. The Otsuka group provides diagnostic agents that meet international standards, including products that support companion diagnostics in a wide range of fields such as for digestive organs, respiratory organs, infectious diseases, cancer, and the cardiovascular system.

\* Companion diagnostics are diagnostic tests used to identify the patients most likely to benefit from a particular therapeutic agent and to determine the optimal dose.



## ADPKD treatment — *Samsca/JINARC/JYNARQUE*

—Taking up the challenge of addressing unmet medical needs—

Guided by our motto of “doing what only Otsuka can do,” the Otsuka group has continued to develop pharmaceuticals with novel mechanisms of action and efficacy for various diseases. *Samsca/JINARC/JYNARQUE* offers a lot of hope as a new drug in the renal field for the treatment of autosomal dominant polycystic kidney disease (ADPKD), a condition for which there was hitherto no known treatment.

### ADPKD characteristics and number of patients

Autosomal dominant polycystic kidney disease (ADPKD) is a rare hereditary disorder in which many fluid-filled sacs (cysts) form in both kidneys, which gradually grow larger, thereby causing symptoms such as pain and a swollen abdomen and eventually leading to a decline in renal function. Around half of ADPKD patients develop end-stage renal failure by the age of 60 and require dialysis or a kidney transplant. The incidence rate of ADPKD is around one person for every 2,000–8,000 people and there are estimated to be roughly 30,000 patients in Japan and about 140,000 in the US.

countries and as a result, the drug was approved in Japan in 2014 and Europe in 2015. In the US, additional clinical trials were requested by the FDA, but it was eventually approved in 2018 and made available to anxiously waiting patients in that country too. The development of this groundbreaking drug has been rated highly by patients and medical professionals alike and in May 2019 Otsuka was selected to receive the Corporate Innovator Award from the US National Kidney Foundation.

Taking an aquaretic drug and turning it into a treatment for ADPKD was an unprecedented challenge and an extremely long road to take, but being the only single therapeutic drug for an incurable disease, it is an extremely encouraging development for both patients and physicians. *Samsca/JINARC/JYNARQUE* is truly a product that embodies our motto of “doing what only Otsuka can do.”

### *Samsca/JINARC/JYNARQUE* — from development to approval

Research on this drug all started when a physician said, “I want a diuretic that excretes only water.” Conventional diuretics used to treat edema had the drawback of causing the excretion of not just water, but also the electrolytes needed by the human body. This was a troubling issue for physicians because it hampered the treatment of illnesses.

We started our research with a focus on vasopressin in 1983 and six years later in 1989 we discovered the lead compound that led to the development of the aquaretic drug that we now have today. Meanwhile, it was not until 2003, or 20 years after research first commenced, that the drug was shown to be effective on ADPKD in mice. Following clinical trials, it was finally approved after a roughly 30-year journey as the world's first therapeutic drug for ADPKD.

The reason why this drug took such a long time to be approved is because there were no existing drugs for treating ADPKD and therefore no full-scale clinical studies had ever been conducted on the disease. That meant primary clinical indicators had to be established. Each condition was cleared in clinical trials conducted on more than 1,400 patients in 15

### *Samsca/JINARC/JYNARQUE* and the Otsuka group's future

Whereas previously patients only had the option of controlling associated symptoms of ADPKD, like high blood pressure, there are high expectations for this first-ever treatment in countries where the product is sold. Up ahead, we intend to promote its proper use among patients and proceed to the next stage of actually saving lives by mainly monitoring the effects of the treatment over longer periods. Moreover, the Otsuka group has concluded a comprehensive partnership agreement with the Japan Kidney Association for the purpose of raising awareness about ADPKD and improving the level of medical care. Under this partnership, we aim to be of further assistance to patients and their families by leveraging the respective strengths and accumulated experience of each party. Guided by our motto of “doing what only Otsuka can do,” we will continue to embrace new challenges in the future.

### Doing what only Otsuka can do —the path to a first-in-class treatment for ADPKD

I applaud the efforts of the clinical development team at Otsuka for the perseverance and diligence in developing tolvaptan for patients with ADPKD. The launch of *JYNARQUE* in the US means that the tolvaptan is now available to patients with ADPKD in Japan, the EU, North America and in several other countries. This launch finally brings the journey to completion for the researchers who started this the program in 2004. In addition, this is a testament to the many patients and healthcare providers who participated in the clinical trials for ADPKD, for without them this dream could never have become reality; we hope that the launch of *JYNARQUE* brings new options to patients with ADPKD. Finally I want to congratulate the commercial team in the US for the success of the launch of *JYNARQUE* and wish them continued success in bringing *JYNARQUE* to ADPKD patients.

**Robert McQuade**  
Executive Vice President & Chief Strategic Officer  
Otsuka Pharmaceutical Development & Commercialization

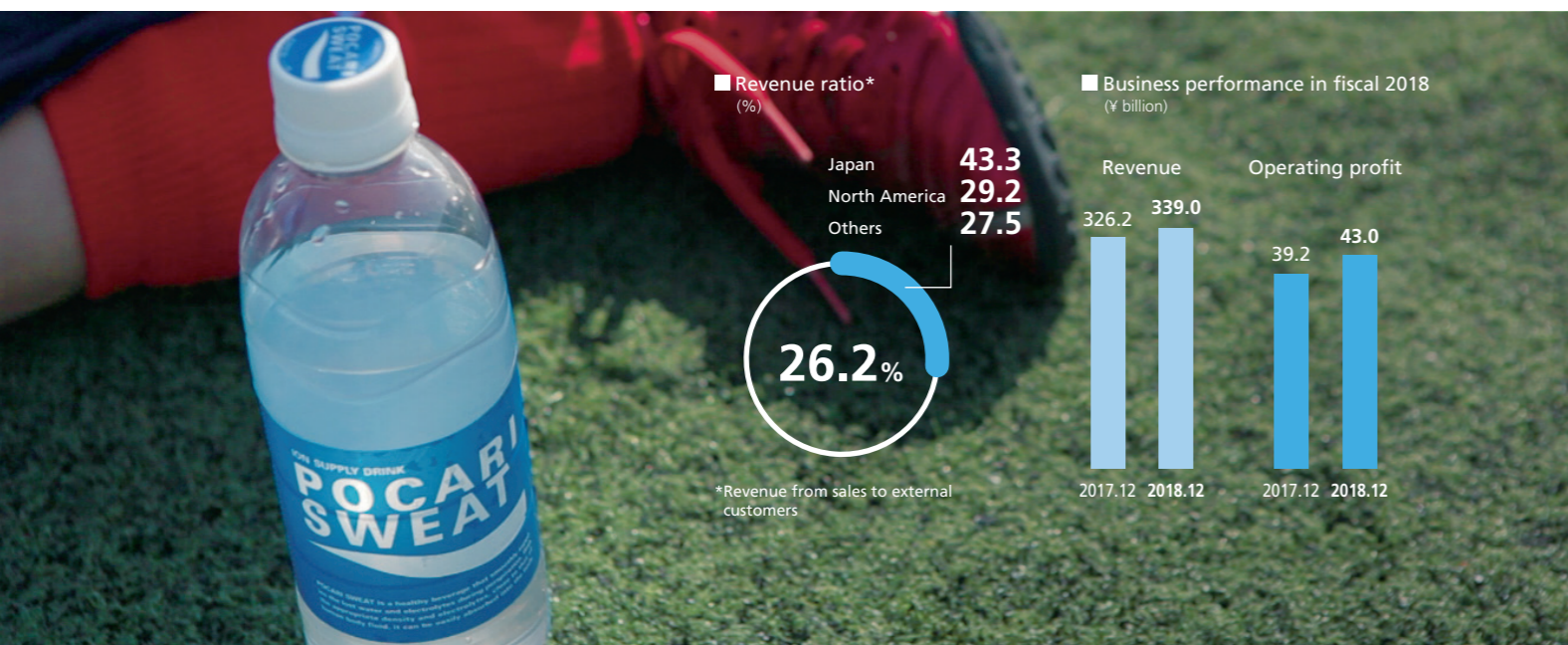


Louis Allesandrino (Vice President of Nephrology and MDD Sales & Marketing, Otsuka America Pharmaceutical, Inc.) receiving an award from Kevin Longino (pictured right), Chief Executive Officer of the US National Kidney Foundation.

# Nutraceutical Business (NC Business)

## Social Challenges/Strengths/Overview

Supporting the management and improvement of everyday health with innovative products based on scientific evidence.



### Social challenges

To be healthy is a desire of all people worldwide. Even though advancements in medical technology and improvements in public health have helped boost global average life expectancies, aging populations and the increase in lifestyle diseases and chronic-phase medical care have pushed up healthcare costs to threaten the sustainability of social security schemes. Given the seriousness of this issue, the importance of managing and improving one's day-to-day health in accordance with cultural and lifestyle habits, as well as life stage, is expected to become increasingly important in the years ahead. Our nutraceutical business (hereinafter referred to as the "NC business") helps the people of the world longevity, healthy, and independent lives by providing innovative products that aim to maintain and improve health, along with beneficial information about human health.



### Otsuka's strengths

#### 1 Innovative products based on scientific evidence

We draw on the know-how accumulated in the pharmaceutical business to develop innovative products based on scientific evidence.

#### 2 Health awareness based on product value

We create innovative, new markets by persistently carrying out product value awareness activities and campaigns in health fields related to our products. We continue to offer new value by partnering with our in-house research institutes and external organizations to conduct research even after product launch.

#### 3 Global network

We contribute to the health of people worldwide by mutually exploiting our own global network and the product attributes, strengths, and infrastructure of each group company to share information about global health issues.

### Product categories

#### Functional beverages

■ Fiscal 2018 sales revenue ¥ **109.4** billion

In the functional beverages category, we mainly develop innovative products based on scientific evidence. Mainstay products include *POCARI SWEAT*, which we developed based on the rehydration drink concept, thus paving the way for a new ion-supply drinks market, *Tiovita Drink*, an energy drink containing taurine, vitamins, and carnitine chloride, *ORONAMIN C DRINK*, a carbonated energy drink containing multiple vitamins, and the high-fiber drink *Fibe-Mini*, a Food for Specified Health Uses (FOSHU) to regulate gastrointestinal condition.



#### Functional foods

■ Fiscal 2018 sales revenue ¥ **75.6** billion

In functional foods, we sell nutrition products and health foods. Mainstay products include *Calorie Mate*, a balanced nutritional food containing five major nutrients that gave birth to a new genre of nourishment, *SOYJOY*, a soy bar that is made from whole soy beans and gives you all the nutrition of soy beans, and a lineup of organic and gluten-free products sold in more than 40 countries by Europe-based Nutrition & Santé.



#### Nutritional supplements

■ Fiscal 2018 sales revenue ¥ **96.1** billion

In this product category, our main brands are *Nature Made*, nutritional supplements free of flavorings, colorings, and preservatives that have passed a rigorous quality-standard process from the procurement of raw materials right through to quality testing, *MegaFood*, supplements derived from natural food sources such as fruits and vegetables, and *INNATE*, supplements marketed to medical institutions.



#### Others, including new products

■ Fiscal 2018 sales revenue ¥ **58.0** billion

We have also developed many other unique products such as *EQUELLE*, which contains equol to support women's health and beauty, *Kenja-no-shokutaku Double Support*, a food for specified health use that slows down the body's absorption of sugar and lipids, thereby reducing the rise in blood glucose levels and triglycerides after a meal, OTC products like *Oronine H Ointment* for treating skin ailments and cuts, and our cosmetics\* concept skincare brands *InnerSignal* and *UL-OS*.



\*Portmanteau of "cosmetics" and "medicine"

\*Our product categories changed in fiscal 2019. Please see our earnings results material for more details.

## Global Expansion

Guided by our philosophy of contributing to the health of people worldwide, we engage in business activities in accordance with the culture and health issues of each region.

### Japan

Average life expectancy in Japan for both men and women is among the highest in the world, but a new challenge for society is now emerging. There is a gap between life expectancy and healthy life expectancy, or in other words, the period during which a person's daily life is not hindered by health problems. The Otsuka group has drawn on its extensive know-how accumulated in the pharmaceutical business to develop innovative products based on scientific evidence.

In recent years, we have continued to conduct research on the key topic of extending healthy life expectancy. Furthermore, in carrying out this R&D, we utilize our accumulated insights to coordinate activities that promote public awareness of the importance of hydration and replenishment of electrolytes for prevention of heatstroke, activities that teach people about the importance of eating well-balanced meals, and initiatives that support women's health with the goal of promoting health and productivity management and the empowerment of women. Not only do we aim to solve health issues in communities by teaming up with local governments, schools, corporations,

and associations, we are also developing new products to provide solutions for the next challenges and undertake initiatives to broaden our interaction with society depending on the circumstances.



Providing information to support women's health

### Asia

In addition to the risks of heatstroke, tropical diseases, and infectious diseases in tropical regions, demand is rising in Asia for hydration and nutrition as a result of more people playing sport and a greater awareness of health issues.

After launching *POCARI SWEAT* in Hong Kong and Taiwan in 1982, we expanded our reach by setting up production sites in China, South Korea, Taiwan, and Indonesia. As of the end of 2018, *POCARI SWEAT* is available in more than 20 countries and region worldwide.

In Indonesia, where we first launched in 1989, our market share in the sports drink category has now increased to 68%\* owing to community-based promotion activities and our efforts to educate consumers about the importance of hydration and electrolyte replenishment. And in order to comply with Indonesia's cultural norms, we



established new halal-certified manufacturing lines for *ORONAMIN C DRINK* and *SOYJOY* at our plant there and commenced production and sales of those products in Indonesia in 2018.

\*Source: Euromonitor International (Retail Value RSP)

■ *POCARI SWEAT* overseas sales volume (10,000 cases)



Share of sales in Indonesia (Sports drink category 2018) **68%**



### North America

In the US where self-medication is prevalent, the self-medication demand continues to increase mainly because of skyrocketing medical costs in recent years.

Pharmavite, a leading company in the US supplement industry, produces supplements based on safety and efficacy by consulting with experts to develop products that incorporate state-of-the-art science. The company's high quality supplements meet the strict quality criteria set by the United States Pharmacopeia (USP) and its leading brand is recommended the most by pharmacists across nine



product categories\*.

Daiya Foods develops, manufactures, and sells high-quality, innovative plant-based food products such as cheese alternatives, yogurt alternatives, dressings, and desserts. The company's product range is enjoyed not only by vegetarians and people with food allergies, but also by health-conscious millennials.

\*2019 US News & World Report—Pharmacy Times Survey. Product categories: Letter Vitamins (A-E), Coenzyme Q10, Omega-3/Fish Oil, Flax Seed Oil, Herbal Supplements, Mood Health Supplements, Diabetic Multivitamins, Garlic Supplements, Cholesterol Management (Fish Oil)



### Europe

The organic food market in Europe has grown in recent years as more health-conscious consumers demand safer and more trustworthy food. Accordingly, so-called free-from foods and alternative products are attracting the attention of millennials—in fiscal 2018 the meat-free food market was worth approximately \$1.3 billion, having grown rapidly over the past five years at CAGR of 12.8%\*, while the gluten-free food market was worth around \$1.7 billion after expanding at CAGR of 14.5%\*.

Headquartered in the south of France, Nutrition & Santé derives its name from the French words for "nutrition" and "health." The company manages a portfolio of 28 mostly health food brands and sells its products in more than 40 countries around the world but with a focus on European markets. At each of its plants, the company has obtained IFS, the international food production standard, to guarantee a high level of product quality management. In 2017 it constructed a new plant in France for the production of gluten-free food. In 2018 it welcomed organic food

manufacturer BC Bio into the group and is catering to expanding consumer needs by strengthening its free-from product range.

\*Source: Euromonitor International (Retail Value RSP)



## R&D Framework —product development based on scientific evidence—

Our NC business research institutes conduct research on topics such as nutrition and exercise from unique viewpoints and utilize the know-how honed in our pharmaceutical business to develop and provide the world with innovative products based on scientific evidence that maintain and improve people's health.

### Saga Nutraceuticals Research Institute

Since its establishment in 1984 as Japan's first private research institute for clinical exercise and nutrition, this facility has conducted R&D activities in various subject fields to address exercise and nutrition, women's health, and other health issues. In 2014 one of the largest artificial environment control rooms in Japan was built at the institute, enabling the re-creation of high temperature/high humidity and low temperature/low humidity environments that may be found in hypoxic environments up to a maximum altitude of 5,000 meters. Such conditions had thus far proved difficult to replicate, but this new chamber will help further research into sports nutrition, such as the effects of fluid and nutritional intake in harsh environments.



### Otsu Nutraceuticals Research Institute

The Otsu Nutraceuticals Research Institute was established in 2000 in order to further research on the topic of gut immunity, with a particular focus on the intestines, which play a key role in life support. Research was conducted on the topic of enhancing the body's biological barrier by increasing the secretion of immunoglobulin A (IgA), an antibody that plays a crucial role in mucosal immunity. Human clinical trials demonstrated that lactic acid bacteria B240 heightens the function of mucosal immunity and lowers the probability of catching the common cold.



### TOPIC

## Using science to support women's vital and energetic lives



**Shigeto Uchiyama**  
Fellow, Saga Nutraceuticals Research Institute  
Nutraceutical Business Division  
Otsuka Pharmaceutical Co., Ltd.

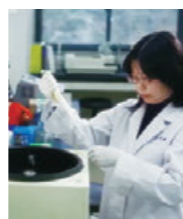
In light of issues such as expanding healthy life expectancy and the advancement of women's empowerment, understanding the field of women's health is growing increasingly important.

Otsuka Pharmaceutical started lending its assistance in 1985 to global joint research studies on cardiovascular diseases and nutrition initiated by the WHO and others and has since explored the numerous possibilities of soy beans over many years by, for example, taking part in projects to elucidate the relationship between diet and longevity. A study focused on isoflavones contained in soy beans conducted by the Saga Nutraceuticals Research

Institute discovered there to be a close relationship between woman's health and equol, an isoflavandiol estrogen metabolized from soy bean isoflavones by bacterial flora in the intestines. The institute successfully isolated lactococcus strain 20-92, a lactic acid bacterium that produces equol. Using this lactic acid bacteria to produce equol by fermenting soy germ, we finally created the equol-containing supplement *EQUELLE* in 2014 after 18 years of R&D in collaboration with pharmaceutical divisions and our US affiliates. In 2018 we launched *EQUELLE Gelée* to further support the fundamentals of women's beauty and health.

Otsuka Pharmaceutical continues to investigate the various possible health benefits of equol.

We hope to offer support to women's health by providing information and developing products that address the various issues at each stage of a woman's life.



Otsuka Pharmaceutical conducts a broad range of studies on maintaining health in women, such as menopausal symptoms, bones and skin, and the health of blood vessels. The following website provides some information on these various studies.

<https://www.otsuka.co.jp/en/health-and-illness/living-well-with-menopause/equil-research/>

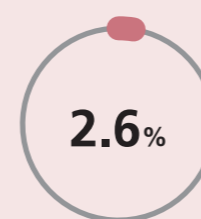


## Consumer Products Business

Our consumer products business delivers familiar foods and beverages that are delicious, safe, reassuring, and healthy.

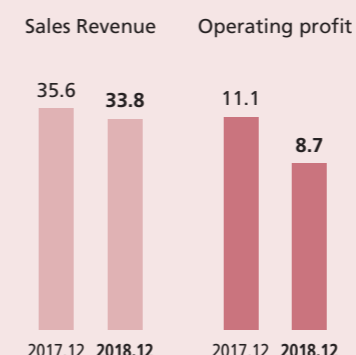


### Sales Revenue ratio\* (%)



\*Revenue from sales to external customers

### Business performance in fiscal 2018 (¥ billion)



### Fiscal 2018 business overview

Sales revenue for the consolidated fiscal year came to ¥33.8 billion (-5.0% YoY). The decrease mainly reflects the impact of a lower domestic sales volume for *CRYSTAL GEYSER* and other mineral water products, despite a year-on-year sales volume increase for the carbonated vitamin drink *Match* owing to higher OTC sales from an aggressive marketing strategy and an improved recipe for the mixed berries flavor *Berry Match*. Operating profit decreased to ¥8.7 billion (-22.0% YoY) owing partly to a decline in equity-method gains.

### TOPIC

## World's first retort curry born out of our sterilization technology and know-how in the intravenous solutions business

In 1968, Otsuka Foods launched sales of *Bon Curry*, the world's first commercially available curry in a retort pouch. Drawing inspiration from the vacuum-packed ready-to-eat sausages used by the military, we applied our sterilization techniques and know-how from our group's intravenous solutions business to successfully develop, through a process of trial and error, a reliable and safe food product that can be easily consumed at home. In developing this product, we insisted that it must not contain preservatives and can be stored for long periods at room temperature. Following the product's launch, our unconventional marketing campaign using enamel signs proved

effective and *Bon Curry* gradually became a staple at Japanese dinner tables.

In 2018, *Bon Curry* celebrated its 50<sup>th</sup> anniversary and to date a total of three billion packs of the product have been sold. Based on the same concept of reliability and safety, the product is still free from preservatives and artificial colorings and all vegetable ingredients in the series are Japan-grown\*. Since 2013 all *Bon Curry* products sold in Japan can now be heated in a microwave oven without the need to remove its cardboard packaging, thus making the preparation of a reliable and safe meal for today's busy families even faster.

\*Excluding the *Ganso Bon Curry* limited to sale in Okinawa



Vintage enamel sign



Removal of sprouts on the potatoes is performed totally by hand



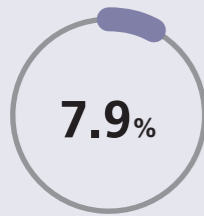
Original retort pressure cookers—pressure and heat sterilization at high temperature enables long shelf life without the use of preservatives

## Other Businesses

Expanding our businesses multilaterally with a focus on chemical products, warehousing, and transportation.

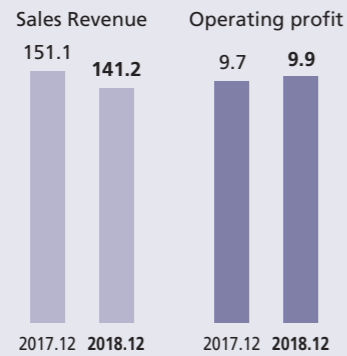


■ Sales Revenue ratio\* (%)



\*Revenue from sales to external customers

■ Business performance in fiscal 2018 (¥ billion)



### Fiscal 2018 business overview

Revenue from functional chemical products increased year on year mainly owing to sales volume growth for products such as hydrazine hydrate and friction materials. Revenue from fine chemicals declined year on year due chiefly to the impact of orders being pushed back. In transportation and warehousing, revenue grew year on year thanks to an increase in the volume of group products handled, as well as expansion of a shared platform for joint distribution with external customers. As a result of the above, sales revenue for the consolidated fiscal year came to ¥141.2 billion (-6.5% YoY) and operating profit to ¥9.9 billion (+1.4%).

## Foundation of Value Creation

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### TOPIC

## Otsuka Warehouse accelerates workstyle reform initiative with completion of Cross Dock Harumi Building

In October 2018, Otsuka Warehouse completed a full renovation of its 40-year-old distribution facility in the Harumi Building in Tokyo's Chuo Ward, transforming it into a new leased office space.

As suggested by the name Cross Dock\*, a logistics industry term, the offices of Otsuka Warehouse were designed with the idea of having employees share information and opinions and broaden their reach in a space where they can interact with different people from within and outside of the company. Not only do all departments work on the same floor where the walls have been removed, the same floor also has a kitchen and café space where employees can openly communicate with each other. Employee presentations are given every day from atop a stage, while from time to time speakers from outside the company also deliver lectures from this spot. The new office therefore functions as a space that can enhance intellectual productivity and the exchange of knowledge it generates also

contributes to Otsuka Warehouse's efforts to develop human resources and promote workstyle reforms.

\*In logistics, a cross-dock facility is one that unloads different cargo from multiple origins and re-sorts each item ready to be shipped to different destinations.



### Human Resource Development Institute

The institute pictured was established with aim of nurturing human resources unshackled from conventional ideas and successful experiences so the Otsuka group can continuously generate innovation and change. The building features some monuments symbolic of this metaphorical paradigm shift, including a giant tomato tree, a bent giant cedar, and floating stones.

# The Otsuka group CSR

— Toward Realizing a Sustainable Society —

The Otsuka group recognizes that CSR is integrated into our businesses and proactively promotes CSR based on our corporate philosophy.

## Corporate Philosophy

# Otsuka-people creating new products for better health worldwide

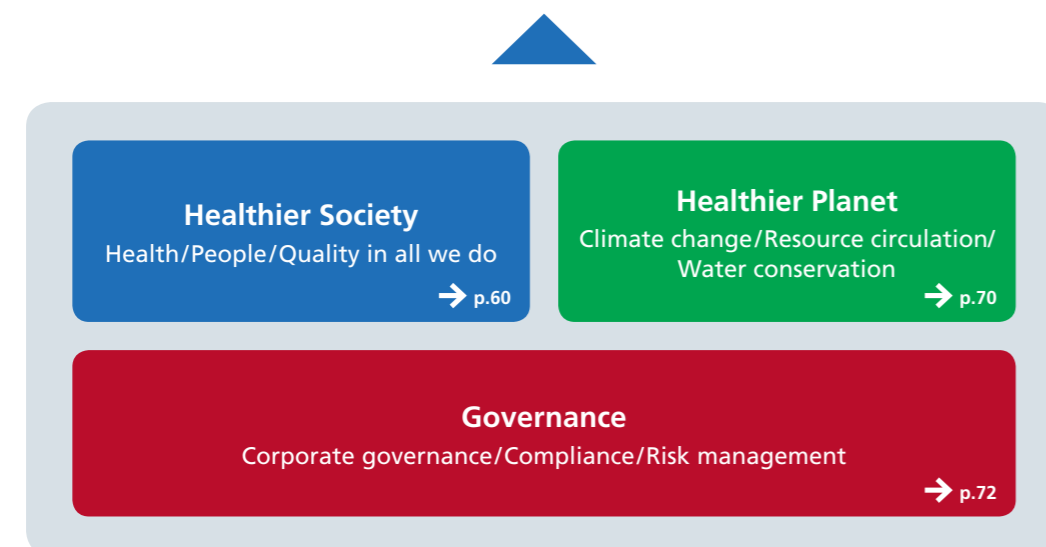
## Otsuka's Goal

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

## Otsuka's CSR mission

CSR is integrated into our businesses across the Otsuka group of companies, which aims to grow while contributing to the creation of a healthy and sustainable society. We pursue these objectives supported by a comprehensive governance system.

Otsuka-people creating new products for better health worldwide



## Otsuka Group's Materiality and Related SDGs

Materiality	Social Issues	Our Goals	Our Activities	Related SDGs	
Society	Health	<ul style="list-style-type: none"> <li>Unmet medical and health needs</li> <li>Spread of infectious diseases</li> <li>Nutritional needs</li> <li>Increasing aging issues</li> </ul>	<ul style="list-style-type: none"> <li>Contribution to unmet needs solution</li> <li>Eradication of tuberculosis</li> <li>Creation of a system for the realization of a healthful life</li> <li>Healthy life extension</li> </ul>	<ul style="list-style-type: none"> <li>Promotion of R&amp;D for unmet needs</li> <li>R&amp;D of antituberculosis drugs and improvement of drug access</li> <li>Support for people's health maintenance / improvement mainly on exercise and nutrition etc., enlightenment activities</li> <li>Promotion of problem solving by strengthening partnerships</li> </ul>	
	People	<ul style="list-style-type: none"> <li>Presentyism*1</li> <li>Unpaired to diversification</li> </ul>	<ul style="list-style-type: none"> <li>Creation of a corporate culture that stimulates creativity</li> <li>Enhance employee engagement</li> </ul>	<ul style="list-style-type: none"> <li>Human resource development</li> <li>Diversity promotion</li> <li>Health management</li> </ul>	
	Quality in all we do	<ul style="list-style-type: none"> <li>Consumption and production that impairs sustainability</li> </ul>	<ul style="list-style-type: none"> <li>Gaining stakeholder trust</li> <li>Pursuing sustainability at all levels of the value chain</li> <li>Establishing a quality assurance system for safety and security</li> </ul>	<ul style="list-style-type: none"> <li>Sustainable procurement and product design</li> <li>Thorough quality control and stable supply</li> <li>Responsible promotional activities and information provision</li> <li>Deepening communication with stakeholders</li> <li>Promotion of "Customer-oriented management"</li> </ul>	
Environ-ment	Climate change	<ul style="list-style-type: none"> <li>Global warming</li> </ul>	<ul style="list-style-type: none"> <li>FY 2030 Goal: 30% reduction in CO2 emissions compared to FY 2017</li> </ul>	<ul style="list-style-type: none"> <li>Reduce CO2 emissions throughout the value chain</li> </ul>	
	Resource circulation	<ul style="list-style-type: none"> <li>Environmental load increase</li> </ul>	<ul style="list-style-type: none"> <li>FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019*2</li> </ul>	<ul style="list-style-type: none"> <li>Reduce environmental impact by improving resource efficiency</li> <li>Promotion of business activities aimed at a sustainable state in both society and the earth</li> </ul>	
	Water conservation	<ul style="list-style-type: none"> <li>Reducing freshwater availability</li> </ul>	<ul style="list-style-type: none"> <li>FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017</li> </ul>	<ul style="list-style-type: none"> <li>Understanding water resources risk</li> <li>Management and effective use of water resources</li> </ul>	
Governance	<ul style="list-style-type: none"> <li>Fragile governance system</li> <li>Social change risk</li> </ul>	<ul style="list-style-type: none"> <li>Long-term improvement of corporate value</li> </ul>	<ul style="list-style-type: none"> <li>Strengthen corporate governance</li> <li>Thorough compliance</li> <li>Risk identification, evaluation and management</li> </ul>		

\*1 The situation where productivity does not go up from the badness of the mind and body condition despite coming to work  
 \*2 Calculated using 2019 as base year

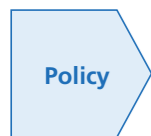
## Support for the United Nations Global Compact

Otsuka Holdings became a signatory to the UN Global Compact in 2016. In this way, we are contributing to the realization of a sustainable society through our business activities, taking into account not only the UNGC's 10 principles, but also the Sustainable Development Goals (SDGs).



### The Ten Principles of the UN Global Compact

Human Rights	Principle 1	Principle 2	Principle 3	Principle 4	Principle 5	Principle 6	Environment	Principle 7	Principle 8	Principle 9	Principle 10
Labour	Businesses should support and respect the protection of internationally proclaimed human rights; and	make sure that they are not complicit in human rights abuses.	Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;	the elimination of all forms of forced and compulsory labour;	the effective abolition of child labour; and	the elimination of discrimination in respect of employment and occupation.	Anti-Corruption	Businesses should support a precautionary approach to environmental challenges;	undertake initiatives to promote greater environmental responsibility; and	encourage the development and diffusion of environmentally friendly technologies.	Businesses should work against corruption in all its forms, including extortion and bribery.



- Seek to resolve global health issues from a total healthcare perspective.
- Do away with deep-seated preconceptions and promote the development of creative human resources.
- Pursue product quality and reliability from the viewpoint of consumers.



## Health

Based on the recognition that CSR is an integrated part of our business operations, the Otsuka group implements CSR initiatives under its corporate philosophy of “Otsuka-people creating new products for better health worldwide”. Health is a universal desire of all people around the world. The Otsuka group engages in activities on a daily basis to prevent and treat disease and to contribute to the maintenance and improvement of people’s health worldwide. The world we live in still faces a host of medical-related issues, such as the spread of infectious diseases, insufficient medical care facilities, and lack of effective therapeutic drugs. In aiming to solve these problems, we constantly ask ourselves what it is that only we can do. Accordingly, we carry out activities to find solutions for unmet medical needs that most companies have yet to address.

Moreover, owing to skyrocketing medical costs, maintaining and improving health is now an issue that society as a whole, not just individuals, must face head-on. Alongside initiatives that raise awareness of health among individuals, the Otsuka group also contributes to initiatives for maintaining and improving health in society at large through collaboration with local communities.

## Pharmaceutical Business

### Challenge of addressing unmet medical needs

#### Psychiatry & Neurology

The sharp rise in patients with central nervous system disorders is now a global issue, highlighted by the decision of Japan’s Ministry of Health, Labour and Welfare to add psychiatric disorders to the big four diseases. However, even though there are many psychiatric and neurological diseases like schizophrenia, depression, bipolar disorder, and Alzheimer’s, they say research and development in this field is challenging because the reasons for their onset are still largely unknown. Furthermore, many are

unsatisfied with how these disorders are treated and patients and their families are eager to try new therapeutic drugs. As a key focus area, the Otsuka group is making headway in the field of psychiatric and neurological diseases, namely with the development of *REXULTI*, an antipsychotic drug, and *Selincro*, a drug for decreasing the amount of drinking for alcohol-dependent patients. We are also embracing the challenge of developing therapeutic drugs for diseases with no curative medicine so far.

#### Oncology

Owing to advancements in medical science, progress is being made year by year on the diagnosis and treatment of cancer, but there are still many patients for which effective treatment methods have yet to be found. For this reason, cancer remains one of the biggest causes of death today. The area of oncology with its currently many unmet medical needs is one of the Otsuka group’s focus areas based on our track record of developing anti-cancer agents that can be administered orally, which at the time were not widely available anywhere in the world. We are

embracing the challenge of working in gene therapy, cellular therapy, and other new areas of treatment by utilizing the diversity of modalities so we can respond to the shift from conventional treatments based on characteristics common to many patients, to treatment that is more personalized. Up ahead, we will endeavor to engage in research and development in order to provide innovative therapeutic drugs as early as possible.

### Infectious diseases

As one of the three major infectious diseases in the world—the other two being AIDS and malaria—tuberculosis is the single most infectious disease, accounting for the highest number of fatalities. After more than 30 years of research and development, Otsuka Pharmaceutical successfully created *DELTYBA*, a new anti-tuberculosis agent. Currently we are advancing research and development for expanding the application of this drug to children, which would be a world-first, as well as new pharmaceuticals for multidrug-resistant tuberculosis. Furthermore,

considering the current situation in which new treatment options for multidrug-resistant tuberculosis are urgently needed, in 2016 we entered into a public-private sector agreement with the Global Drug Facility (GDF) of the Stop TB Partnership. We are also pursuing drug approvals in multiple countries, and currently through access programs deployed by government and public international institutions and expanded access by alliance partners, the use of *DELTYBA* is being promoted in over 80 countries.

### Initiatives for supplying pharmaceuticals to even more patients

With the aim of contributing to improved access to pharmaceuticals, the Otsuka group is engaged in research and development of therapeutic drugs and IV solutions to address unmet needs. We are also undertaking initiatives to provide pharmaceuticals at fair prices and establish healthcare infrastructure.

For example, the local manufacture of IV solutions\*—defined as a basic pharmaceutical with high clinical necessity whose manufacturing and sales will continue to be required

without interruption—contributes to fair pricing in each country and also creates employment. Even though there are not many Japanese pharmaceutical companies supplying locally manufactured drugs because of the risks and differences in technological know-how, Otsuka Pharmaceutical Factory is committed to the local manufacture of IV solutions based on its ambition to supply pharmaceuticals at fair prices for each country or region so that any person, rich or poor, can have equal access to healthcare.

\* Vision for the Pharmaceutical Industry 2013 (Ministry of Health, Labour and Welfare)

### Partnerships

The Global Health Innovative Technology Fund (GHIT Fund) is an international public-private partnership involving the Japanese government and private corporations, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the United Nations Development Program specializing in funding research and development

of drugs and diagnostic drugs and so on to combat the spread of the big three infectious diseases and neglected tropical diseases mainly in developing countries by leveraging Japan’s high level of technology and innovation. Since June 2016, Otsuka Pharmaceutical has contributed to the GHIT Fund as an associate partner.

## Nutraceutical Business

### Initiatives for Yet-To-Be-Imagined Needs

#### Community-based health maintenance and promotion initiatives

Given the surging costs of healthcare and Japan’s aging society, the Otsuka group is promoting community-based health maintenance and promotion initiatives, disaster prevention and disaster relief activities. For example, Otsuka Pharmaceutical has carried out various health awareness-raising and educational activities throughout Japan, leveraging its insight and know-how in areas

such as nutritional education, prevention of lifestyle diseases, measures for avoiding heat disorders, sports promotion, women’s health, and disaster preparedness. As of May 31, 2019, the company has concluded partnership agreements with 45 prefectures in Japan.

#### Preventing heat disorders

The Otsuka group conducts educational activities for people of all ages, from children to seniors, to raise awareness about the importance of replenishing hydration and electrolytes. For more than 25 years since the 1990s when the term “heat disorders”

was still relatively unknown, Otsuka Pharmaceutical has engaged in activities to prevent and treat heat disorders. Company employees visit sites to give seminars on the importance of hydration and electrolyte replenishment based on our research



results at our own laboratory and so on, in the area of ion supply drinks. These seminars mainly target athletes, coaches, construction workers, factory workers, people who work under hot conditions, the elderly, and other people at risk of heat disorders. In addition, Otsuka Pharmaceutical Factory, which sells oral

### Women's health

As women continue to play more active roles in society, an environment needs to be established in which women can remain active but at the same time engage in child-raising, nursing care, and deal with their own health issues. However, their professional and personal lives are often disrupted by abnormal bodily rhythms and anxieties about their physical condition. In particular, the care they receive during the midlife transitional period, a time of significant physical and mental change, has an impact on women's healthy life expectancy. The Otsuka group implements initiatives aimed at helping women to lead healthy and active lives, including seminars and the development of products, etc.

rehydration drinks, supports organizing the activities of the Committee for Awareness of Hidden Dehydration, which works to raise awareness of ways to prevent and treat dehydration before it becomes critical.



A health seminar

## Group-wide Initiatives

### Otsuka Health Comic Library

The Otsuka Health Comic Library which helps children to deepen their interest in and understanding of how their bodies work and their health, has been published every year since 1989 and is celebrating its 30<sup>th</sup> anniversary in 2019. One volume is published every year. Japan Medical Association and Japanese Society of School Health supervise it, Japan Pediatric Association recommends it, and is donated to approximately 23,000 elementary schools and libraries nationwide. Furthermore, comparative table is made to compare to course of study, so it is used not only as reading material for children but also as a teaching aid for science and health classes. We have held health education workshops for elementary school nurses and other school officials since 2015 to propose health education using Otsuka Health Comic Library.



Otsuka Health Comic Library

<https://www.otsuka.com/jp/comiclibrary/> (In Japanese only)



### Disaster relief

In light of our obligation as a company that handles items needed during emergencies, such as IV solutions, pharmaceuticals, foods and beverage, we actively engage in disaster relief activities and disaster victim assistance.

## People

The Otsuka group believes that the creation of innovation and sustained company growth come from the activities of a diverse range of employees in a free and open-minded workplace environment. To this end, we aim to foster a corporate culture that rouses an appetite for creativity. We not only invest in the development of human resources, but we also actively promote diversity in our workforce. As well as establishing a safe working environment, we also make efforts to realize fair hiring, evaluation, and promotion of employees, respecting human rights.

## Development of Human Resources

### Basic Policy

At any point in history, innovation is always generated by people. The Otsuka group would like to continuously create innovation

by attracting talented personnel and developing and flourishing the abilities of each individual continuously.

### Approach

Alongside medium- to long-term business investments, the development of next-generation executive human resources is essential if we are to constantly achieve creative, innovative, and sustained growth in the Middle and Longer- Term, as well as significant growth in corporate value. In 2016 we launched Otsuka Global Academy, human resource development program, with the aim of early identifying and nurturing talented personnel that will underpin the development of the next generation. Executive human resource development programs, Senior Leadership Program and Middle Leadership Program are produced and run in-house across the Otsuka group, but also aims to realize effective HR development through collaboration with external agencies. The program emphasizes the handing down of corporate culture and seeks to identify the kind of candidates required to lead the Otsuka group in the future. As of the end of May 2019, over 100 employees from the group had participated in the program. And in the area of supporting self-directed learning, in 2017 we launched the OGA Self-Learning Syllabus, a platform that Otsuka group employees can utilize to find information about learning English or improving their business skills, among other things. We are building an educational framework that reflects the characteristics of each group company's business so that each member of our diverse workforce can continue to

develop and demonstrate their respective skills. We have also established an open recruitment system\*1 and self-assessment system\*2 for the purpose of enhancing the capabilities of each employee.

At Otsuka Pharmaceutical, the Human Resources Department employs a system of following up on opinions voiced by employees by holding individual meetings with every employee. We are also making efforts to maximize the development of global human resources and our organizational capabilities with the introduction of a new system to centrally manage HR information on a global level so that all of our employees worldwide can play a more active role. Otsuka Pharmaceutical Factory is working to enhance the management skills of its leaders with the implementation of a 360-degree feedback system for its department managers, who receive multi-faceted feedback from multiple people with differing positions and relationships.

\*1 Under this system, the Otsuka group discloses in advance the conditions of a certain posting or job and then appoints the required number of people from among those who applied. Employees that satisfy the requirements can apply directly to the company offering the position and be transferred if expectations of both parties are in agreement. The open recruitment system can be utilized by any person working at the Otsuka group companies in Japan and aims to boost employee skills and motivation and invigorate interaction between the Otsuka group employees.

\*2 Under this system, employees can provide information to the Human Resources Department about their current work duties, offer opinions and suggestions regarding their workplace, and describe their career plan aspirations. The self-assessment system is implemented once yearly with the goal of further developing employee skills, assigning employees the right jobs, and improving the workplace environment.

## Diversity

### Basic Policy

The Otsuka group actively promotes diversity based on the belief that the activities of a wide range of employees further advances innovation and globalization. Accordingly, as a company

constantly in pursuit of innovation, we are endeavoring to establish a workplace environment brimming with diversity.

### Approach

Since the 1980s when the concept of diversity had still yet to take off in Japan, the Otsuka group's top management has continued to actively promote diversity, with for example the hosting of the Women's Forum in 1990, based on the thinking that the efforts of a diverse workforce made up of different nationalities, races, ages, gender, disabilities, or sexual orientation is needed if the group is to create innovative products and ideas that drive company growth.

The Otsuka group has proclaimed its promotion of diversity in the Otsuka Group Global Code of Business Ethics and in 2017 became a signatory to the Women's Empowerment Principles (WEPs\*1), a set of corporate principles jointly developed by the UNGC\*2 and UN Women\*3 to offer guidance on how to empower women in the workplace.

In order to lengthen the careers of our diverse workforce, we have enhanced the childcare and nursing care systems at each of the Otsuka group companies and have opened three

daycare centers located within our business premises to help employees balance child-rearing and work.

Other initiatives include, the formation of Cancer Patient Employment Support Team at Taiho Pharmaceutical, a company that develops and sells anti-cancer agents. This team, comprised of the Human Resources Department and occupational nursing staff, aims to create a workplace where an employee suffering from cancer or other disease can continue to work while still receiving treatment. After establishing this support framework, the company has been recognized in the "Excellence Award" category as having outstanding initiatives that help cancer patients balance treatment and work.

Furthermore, Heartful Kawauchi was established in 2011 in Tokushima as a special subsidiary of Otsuka Pharmaceutical. This subsidiary provides a place where disabled people can fully demonstrate their capabilities.

\*1 Women's Empowerment Principles  
 \*2 United Nations Global Compact  
 \*3 United Nations Entity for Gender Equality and the Empowerment of Women

### Approach

The main Otsuka group companies have a health declaration under which it strives to create a workplace environment conducive to maintaining and improving the health of all employees. As part of this initiative, Otsuka Holdings engages in activities aimed at improving the health of employees by collaborating with the Otsuka Pharmaceutical Health Insurance Association, medical professionals, and those in charge of health management at each company. One such activity is the hosting of health seminars for group employees and their families. They are held in Japan's major cities nationwide and provide information about the group's initiatives on health, an introduction to the health insurance association, and information that can improve the health of employees and their families. Another activity is the group-wide Tokushima Health Project, known as TOK-J, which started in 2017. The theme of the project is "creating a lively and cheerful workplace by alleviating the risk of lifestyle diseases." The project kicked off with two approaches: 1) improving the health of employees susceptible to metabolic syndrome in the Tokushima area (where the majority of the Otsuka group employees live and work); and 2) raising awareness of health issues in the area overall. The project recommends walking and exercise and offers guidance on healthy eating.

Furthermore, from the perspective of creating a safe and

reassuring workplace, Otsuka Chemical, for example, opened its Anzen Dojo (Experience-based Safety Training Center) in 2012. This center runs training sessions for group employees, employees of overseas affiliates, and third parties with the aim of improving safety awareness. Through classroom instruction and simulations of past accidents, the center reaffirms the experience of failure and safety awareness, heightens sensitivity to danger, and develops the ability to anticipate things one step ahead. In recognition of its activities to improve health and safety education and establish a safety culture, Otsuka Chemical received the 8th Responsible Care Excellence Award from the Japan Chemical Industry Association in 2014.



Tokushima Health Project (TOK-J)

### External Recognition

	<p><b>Platinum Kurumin &amp; Kurumin</b>                  (Ministry of Health, Labour and Welfare, Tokyo Stock Exchange)</p> <p>A system whereby the Ministry of Health, Labour and Welfare certifies companies that meet certain standards by formulating and notifying action plans based on the Act on Advancement of Measures to Support Raising Next-Generation Children.</p> <p>Platinum Kurumin is a certification for Kurumin certified companies that have carried out higher-level initiatives.</p>	<ul style="list-style-type: none"> <li>•Platinum Kurumin: Otsuka Pharmaceutical Factory, Taiho Pharmaceutical</li> <li>•Kurumin: Otsuka Pharmaceutical, and others</li> </ul>
	<p><b>Eruboshi</b>                  (Ministry of Health, Labour and Welfare)</p> <p>A system that certifies companies that meet certain standards and recognizes efforts to empower women in the workplace under the Act to Promote the Active Participation of Women in the Workplace.</p>	<p>Otsuka Chemical: Grade 3 (top rank)</p>
	<p><b>Semi-Nadeshiko</b>                  (Ministry of Economy, Trade and Industry, Tokyo Stock Exchange)</p> <p>A system for selecting companies that conform to the Nadeshiko Brand of encouraging women's success in the workplace</p>	<p>Selected in 2019: Otsuka Holdings                  *Limited to Otsuka Holdings and Otsuka Pharmaceutical</p>
	<p><b>Diversity Management Selection 100</b>                  (Ministry of Economy, Trade and Industry)</p> <p>A system that recognizes companies that have improved corporate value through diversity management</p>	<p>2014 Award: Otsuka Pharmaceutical</p>

### External Recognition

		<p><b>Excellent Corporation for Health Management</b>                  (Ministry of Economy, Trade and Industry, Nippon Kenko Kaigi)</p> <p>A system that recognizes corporations that practice exceptionally good health management</p>	<p>Certified in 2019: Otsuka Holdings, Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Electronics, JIMRO, Otsuka Wellness Vending</p>
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## Health and Safety

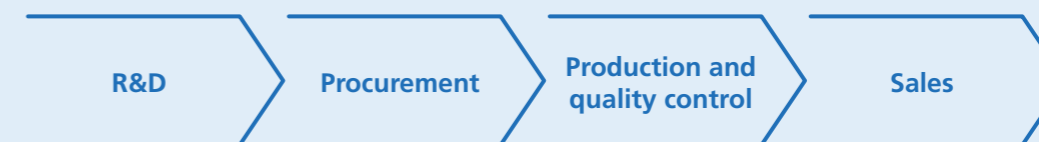
### Basic Policy

The Otsuka group recognizes that the mental and physical well-being of each and every employee is indispensable to realizing our shared corporate philosophy of "Otsuka-people creating new products for better health worldwide". To this end, we are

committed to creating a safe workplace environment and are continuously implementing initiatives that maintain and improve the health of our employees.

## Quality in all we do

To build sustainable society, the Otsuka group is seeking for sustainability by addressing environmental, social issues and striving to establish quality assurance structure for reassurance and safety at every stage of the value chain.



## Research and Development

### Ethical considerations concerning appropriate R&D

The use of experimental animals to verify efficacy and safety in R&D is at times necessary. The Otsuka group complies with all

related laws, ordinances, and guidelines while striving to uphold scientifically valid methodologies and ethical considerations from

the viewpoints of animal protection and welfare, including the lives of the animals; preservation of the environment; and the safety of experimenters.

As an in-house management system, we have developed and implemented rules on experiments that involve animals, have established an Animal Experiment Committee, and properly carry out animal experiments and breeding. The Animal

Experiment Committee evaluates whether each proposed animal experiment plan is appropriate based on the 3Rs principles. These are Replacement/avoidance or replacement of animal use, Reduction/minimization in the number of animals used, and Refinement/minimization of animal suffering. Based on these, we conduct researcher education and internal inspections and evaluations of the implementation of experiments involving animals.

### Ethical considerations in research using human-derived specimens

When conducting research using information or specimen collected from the human body, such as tissues and blood, the Otsuka group complies with all laws and guidelines and conducts scientifically and medically appropriate research with consideration of ethics. Each group company establishes committees that include outside members to ensure the appropriateness and

credibility of research. The committees do so by examining research plans, the significance and goals of research, personal information management system, research progress status, and research outcomes from the standpoints of ethical and scientific validity and of protection of personal information.

### Considerations in research using pathogenic microorganisms/genetically modified organisms

In experiments using genetically modified organisms, and in the use of pathogenic microorganisms or research samples that may contain these, the Otsuka group complies with laws and ordinances, and works toward the prevention of experiment-related

accidents and toward consideration of the environment. We do so through the setting of internal rules and through examination by safety committees and screening committees.

### Ethics in development

In the development of pharmaceuticals, we confirm the safety and effectiveness of candidate compounds by conducting clinical trials with the cooperation of healthy individuals and patients. Recognizing the importance of ethical considerations toward

human rights and personal information, the Otsuka group implements clinical trials in compliance with ethical principles and standards, including ICH-GCP, an international standard for the implementation of clinical trials for pharmaceutical products.

## Procurement



### Basic Policy

The Otsuka group, together with its business partners, aims to contribute to the building of a sustainable society by promoting CSR procurement that takes into consideration factors such as

legal compliance, the environment, and the protection of human rights.

### Approach

The Otsuka group engages in business activities that are safe, reliable, socially acceptable, and in compliance with laws and regulations across the entire value chain. When commencing dealings with a business partner, we perform screening and checks to ensure the quality of raw materials and to guarantee stable procurement. We also conclude a basic transaction agreement in advance. In the case of a new supplier, transactions are only determined after we have carried out due diligence beforehand. In seeking mutually sustainable development through fair, equitable, and transparent procurement and the establishment of

healthy relationships, we have formulated and share with our business partners our group-wide Otsuka Group Sourcing / Procurement Vision & Policy, which takes into account factors such as human rights, labor issues, the environment, and anti-corruption measures. We have also formulated our Sourcing / Procurement Guideline that embodies the provisions of our policy and plan to hold information sessions in the future for our business partners.

We conduct surveys on business partners by using the CSR procurement self-assessment questionnaire\* provided by UN Global Compact Network Japan—in 2018 more than 95% of

our partners sent back their responses. We assess our business partners with respect to not just legal compliance but their activities regarding human rights, labor, the environment, and anti-corruption measures. And by providing feedback we are further encouraging CSR procurement.

Moreover, in order to ensure a stable supply of products, we perform risk assessments on key raw materials in advance to

identify potential risks so we can take countermeasures. And in principle, we purchase raw materials from multiple companies.

We also take environmental considerations into account. For example, Otsuka Pharmaceutical collaborates with the e-Commerce Department to make suggestions about environmentally friendly packaging.

\*Questionnaires are sent to business partners that correspond to predefined criteria.

### Otsuka Group Sourcing / Procurement Vision & Policy

Based on the corporate philosophy “Otsuka-people creating new products for better health worldwide” and global CSR standards, Otsuka Group will conduct the sourcing / procurement activities to contribute to building a sustainable society and to the people’s health improvement and QOL. Otsuka will strive to provide products with sufficient quality that are innovative, reliable and safe.

#### 1. Relationship with Suppliers

We will build a relationship of trust with our suppliers within the value chain through open and fair communication to aim for mutual sustainable growth.

#### 2. Supplier Selection Criteria

We will select fair and transparent companies for our suppliers by comprehensively evaluating quality (Q), cost (C), delivery (D), and business stability.

#### 3. Consideration for Society

To achieve a sustainable society, we fulfill our social responsibility for human rights, labor, environment and support for local communities.

#### 4. Compliance

While abiding all the laws and regulations, we will thoroughly eliminate unfair transactions and behave with high ethical standards.



## Production and Quality Control

### Basic Policy

The duty of a healthcare company is to always put its customers first. In pursuing product quality and safety, the Otsuka group has established a production and quality control system suited to

the characteristics of each of our business lines, namely, pharmaceuticals, foods, beverage, chemicals and, cosmetics.

### Approach

The Otsuka group’s production, quality, and safety control systems comply with legal requirements and governmental and industry standards (including Japan’s Pharmaceutical and Medical Devices Act (PMD Act) and Japan’s Food Sanitation Act). The group is also working to acquire international certifications such as ISO9001 for quality, ISO13485 for medical devices, and ISO22000 and FSSC22000 for food safety. Furthermore, in order to ensure thorough quality control, we employ a traceability system covering all stages of the product lifecycle, from raw material procurement to production, distribution, and sale. Group-wide global production meetings are held regularly to share various issues and case examples related to production at our plants in order to provide the latest information about production control and prevent issues from occurring. In addition, we provide regular training to relevant employees from health and safety to GMP\*, environmental protection, food safety, compliance, ISO standards, and so on.

Our major group companies that operate on a global scale have also established and operate global quality assurance systems. For instance, Global Product Quality Meeting was held in 2019 at Otsuka Pharmaceutical and attended by around 100 people, including managers and quality supervisors, to discuss quality issues and future initiatives. In our Pharmaceutical

Business, we established global product quality policies for each area in 2017. In addition to product quality, we also aim to improve the quality of clinical practices and IT operations that handle clinical data and we are constantly making improvements by globally managing quality benchmarks. In the Nutraceutical Business, we utilize our global network to draw up guidelines and establish benchmarks for monitoring quality control activities and strive to constantly improve quality through mutual knowledge and inspection. Owing to differences in systems and regulations in each country and region, we encourage each of our plants to acquire international standards, such as ISO9001, FSSC22000, and ISO14001 (environment). We also perform internal audits on our plants on a periodic basis.

As for inquiries about our products from customers, we have in place a framework that further improves the value of our products. More specifically, we confirm with our product quality departments about how the product lot was manufactured, analyze the returned item, compare it with other products in storage at the plant, analyze the cause of the issue, and come up with future countermeasures.

\*Good Manufacturing Practice

## Sales



### Basic Policy

We believe the Otsuka group is obligated to provide high-value products and services to our customers by engaging in

suitable and legally compliant promotions and advertising and communicating with customers in an appropriate manner.

### Approach in Pharmaceutical Business

The Otsuka group has expanded on the JPMA Promotion Code for Prescription Drugs—a code of behavior for healthcare professionals—to formulate its own Code of Practice at each of the group companies in an effort to engage in appropriate collaboration based on relationships of trust with all stakeholders, including medical practitioners. Given that the clarification of relationships between pharmaceutical companies and healthcare organizations is a matter of social responsibility, we are striving to ensure adherence to standards in order to fulfill our responsibility as a pharmaceutical company and ensure the practice of proper medical care based on ethics and a patient-oriented commitment. Furthermore, in addition to abiding by legislation in each country, for example in Japan, Japan’s Pharmaceutical and Medical Devices Act (PMD Act), we engage in quality control and post-manufacturing safety control in accordance with GQP\*<sup>1</sup> and GVP\*<sup>2</sup>

standards, report to the regulatory authorities, and develop and revise various documents. And we have established a system that allows us to constantly perform pharmacovigilance (PV\*<sup>3</sup>) on a global level to collect and assess product safety information, including side effects. In this way, we continue to swiftly provide the results of our monitoring to medical institutions etc. To make sure these activities continue without a hitch, we also implement training every year for relevant personnel. For example, at Otsuka Pharmaceutical, in addition to the aforementioned training, the company conducts annual training related to PV for all employees based on the thinking that every employee is accountable for ensuring the safety of our pharmaceutical products.

\*1 Good Quality Practice  
\*2 Good Vigilance Practice  
\*3 Pharmacovigilance

### Measures against counterfeit drugs

Counterfeit drugs\* have become an issue for the international community. Not only do they fail to provide the expected therapeutic effect, but they put the patient’s health and life at risk. In combatting counterfeit drugs, the Otsuka has launched a global product security team (which also involves overseas group companies) to prepare for the structure to deal with countermeasures.

Collaborating with market surveillance agencies, industry bodies, and governments, we are making an effort to ensure patient safety and to make sure its pharmaceuticals reach the hands of its patients through the appropriate distribution channels that guarantee product quality.

\*Any pharmaceutical product that deceptively represents its authenticity or origin, such as drugs that do not contain the ingredients shown on the label or those that contain active ingredients other than those shown on the label.

### Approach in Nutraceutical Business and Consumer Products Business

In similar fashion to the Pharmaceutical Business, we have established a dedicated unit comprising multiple departments to review marketing plans and sales promotion materials for products in our Nutraceutical and Consumer Products businesses. This ensures that our marketing and sales promotion activities are appropriate and comply with laws and regulations.

Moreover, Otsuka Pharmaceutical, which develops products that deliver health value based on scientific grounds, has established an “Scientific Affairs Department” to gather and disseminate information about products, related knowledge, and the latest academic information. This department also holds monthly information sessions for employees.

### Communication with patients, medical professionals, and customers

The Otsuka group recognizes that enhancing mutual communication with customers and responding to their opinions with sincerity further improves the value of our products and by extension, contributes to people’s health, our society, and local communities. In 2018 we published our “Declaration of

Customer-centric Commitment” to clearly express our stance on undertaking such initiatives.

In the Pharmaceutical Business, in order to minimize problems and risks associated with product quality, safety, and usability experienced by patients and healthcare professionals

alike, we periodically share the details of inquiries, specific opinions of users, and product safety information with our sales staff, safety control departments, and quality assurance departments. We also analyze the inquiries we receive from customers and take steps to improve our products. To provide an example, Otsuka Pharmaceutical received inquiries about its *Meptin* aerosol inhaler used to treat asthma attacks. It was discovered that the product failed to spray or function properly mainly because foreign substances were entering the inhaler through the mouthpiece and the dose counter would not tick over when the user failed to press down far enough. As a result, we made changes to the product’s labelling and made improvements to its internal structure.

In the Nutraceutical Business, dedicated departments for each product line at each of our group companies handle customer inquiries and hold periodic employee training sessions

The product sprays even when the dose counter fails to tick over as the user does not press all the way down on the inhaler. For this reason, we included easy-to-read instructions on the outside of the inhaler asking users to press all the way down.



focusing on related laws and regulations. The inquiries and opinions of customers are also submitted to the relevant departments as feedback and reflected in future product developments and improvements. For example, Taiho Pharmaceutical adopted new specifications to reduce the sharpness on the edges of individual cases and exterior cardboard packaging for its *Tiovita* series so that customers would not cut their fingers when opening the product.

As for inquiries about defective products, returned items are analyzed by our quality control departments and compared with other products in storage. We then consider countermeasures in light of the reason for the defect.

The Otsuka group makes every effort on a daily basis to conscientiously and swiftly respond to customer inquiries and feedback in a manner that is easy to understand. For instance, Otsuka Pharmaceutical is now leveraging the use of artificial intelligence (AI) to provide customers with an even better quality of service. Our AI system offers up common or high-priority responses based on the nature of a customer’s inquiry, which enables our operators to respond more quickly and accurately.

## Declaration of Customer-centric Commitment



### Corporate Philosophy

In the spirit of our corporate philosophy, “Otsuka-people creating new products for better health worldwide”, the Otsuka group of companies provides innovative products and services that contribute to more rewarding, healthier lives for people everywhere, aiming to maintain the trust of our customers and society.

### Policies

#### 1. Commitment from our Leaders

We conduct our daily business with constant attentiveness to what patients and customers truly desire. We continue to uphold Otsuka’s culture of actualization and creativity as a company involved in all aspects of health, from the treatment of illnesses to the maintenance and promotion of healthy lifestyles. We are dedicated to becoming an indispensable company, contributing to better health and quality of life for people around the globe.

#### 2. Corporate Governance

Our basic policies dictate that we fulfill our social responsibilities through honest and trustworthy dialogue with customers, business collaborators, employees, local communities, and shareholders; and that we do so through transparent, fair, and timely decision-making.

#### 3. Inculcate Values in Employees

We have grown as a business by drawing upon the power of our highly diverse workforce. We remain committed to fostering the social and business mindfulness of employees so that we may stay abreast of prevailing values and true customer needs in order to create new categories of products and services.

#### 4. Interactive Communication with Customers

Applying knowledge and know-how accumulated through years of research and business, we conduct mutual communication activities including seminars, factory tours, and online communications to encourage people to become more aware and informed about their health. We have also established points of contact for inquiries, consultations, and feedback to enhance our products and services.

#### 5. Coordination and Cooperation for Rapid Problem-Solving

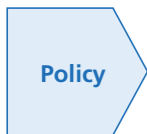
As a health-related company, we always put patients and consumers first, prioritizing the safety of our products. If any issues come to light, we marshal all resources so that we may quickly and efficiently provide solutions and develop ever-better products and services.

October, 2018



# Environment

(Healthier Planet)



**Aiming to be an indispensable company to contribute to the health of global people, the Otsuka group engages in business activities voluntarily, positively and continuously with creativity considering global environment through value chain. We are committed to shaping a sustainable society.**

## Otsuka Group Global Environmental Council

As a group of global companies that contribute to the health of people worldwide, the Otsuka group works sincerely to reduce the impact we have on the global environment through our businesses, and hopes to contribute to the creation of a sustainable society that can protect the nature and the future of the earth.

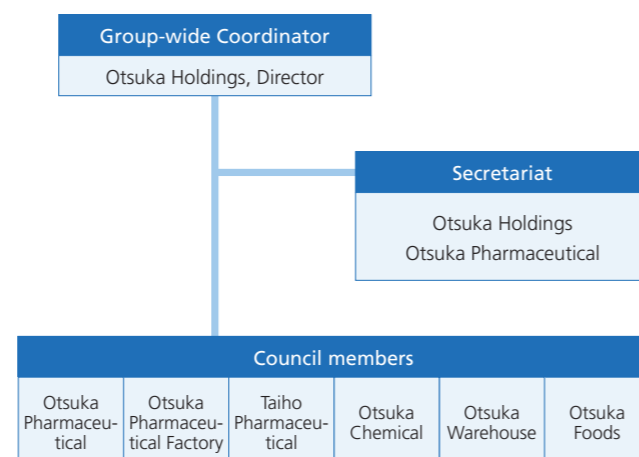
The Otsuka Group Global Environmental Council—comprising a director of Otsuka Holdings, executive officers from each group company, and a secretariat—formulated the Otsuka Group Environmental Policy and Guidelines and advances initiatives on environmental management through collaboration between Otsuka group companies.

The Otsuka group has identified climate change, resource circulation, and water conservation as the CSR Materiality in its environmental initiatives. We have kicked off deliberations on the formulation of a long-term environmental vision that is consistent with the principles of the United Nations Global Compact, information disclosure under global standards, and the setting of medium-term environmental targets with specific action plans slated for launch in 2019.

Looking ahead, we will strengthen and practice environmental management that meets our social responsibilities and the

demands of a global society by deepening the understanding and recognition of environmental problems through environmental education for employees and by further enhancing collaboration between our group companies.

### Council Organization



## Climate Change

FY 2030 Goal: 30% reduction in CO<sub>2</sub> emissions compared to FY 2017

We recognize that the Otsuka group, which conducts business on a global scale, faces significant risks from the impact of climate change. Accordingly, we are formulating long-term reduction targets and action plans for achieving those targets. Moreover, in aiming to realize a carbon-free society, we promote thorough energy-saving measures and endeavor to alleviate our impact on the environment with the use of renewable energy.

## Initiatives for energy use optimization and CO<sub>2</sub> reduction

In Tokushima Prefecture where the production sites of the group are concentrated, Otsuka Chemical and Otsuka Pharmaceutical Factory supply electricity and steam to neighboring group companies with the use of cogeneration systems they installed. Initiatives overseas to promote efficient energy use and reduce CO<sub>2</sub>

emissions across the group include the use of the Joint Crediting Mechanism (JCM)\* and the installation of highly efficient equipment at P.T. Otsuka Indonesia.

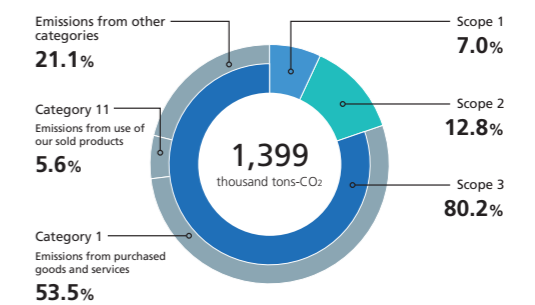
\*A system to work with developing countries for reducing greenhouse gas emissions, in which the result of reduction is assessed as contribution by both partner countries and Japan

## Third-party verification of GHG emissions

In order to improve the transparency and reliability of its environmental data, the Otsuka group is subject to the verification of greenhouse gas (GHG) emissions (Scopes 1 and 2, and categories 1, 2 and 11 of Scope 3)\*<sup>1</sup> by third-party organization. We also implement initiatives aimed at understanding and improving the trends in our emissions. We will continue to expand the scope of verification and further enhance the reliability of our data.

\*1 Scope 1: Direct emissions  
Scope 2: Indirect emissions from energy sources  
Scope 3: Other indirect emissions  
\*2 5 companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods

### GHG emissions throughout the value chain in fiscal 2018\*\*



## Resource Circulation

FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019

In aiming to achieve a sounded material-cycle society, we are working to improve our resources usage efficiency, reduce the generation of waste, promote 3R (reduce, reuse, and recycle) initiatives, and achieve a final waste disposal volume of close to zero in an effort to realize zero emissions (our in-house definition of a recycling rate of at least 99%).

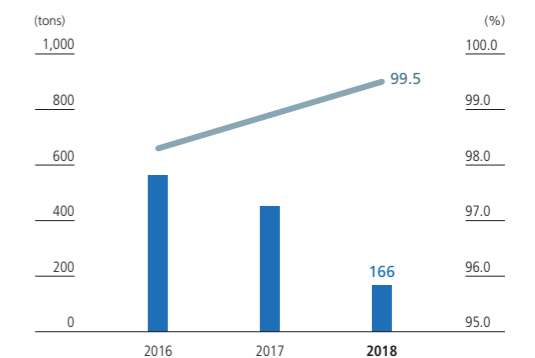
## Initiatives aimed at zero emissions

The Otsuka group companies carry out material recycling\*<sup>1</sup> and thermal recycling\*<sup>2</sup> of generated waste as required.

In fiscal 2018 our 14 group companies in Japan achieved zero emissions with a recycling rate of 99.5%. They have also reduced their total waste volume by around 7,400 tons, a year-on-year reduction of 16%. The group will continue to work on bringing waste down to minimize disposal volume through activities that enhance the efficient use of resources across all our businesses.

\*1 The processing and reuse of waste as raw materials or ingredients.  
\*2 The use of thermal energy generated from incineration of waste.  
\*3 14 major consolidated subsidiaries in Japan

### Resource recycling rate and final disposal amount\*<sup>3</sup>



## Water Conservation

FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017

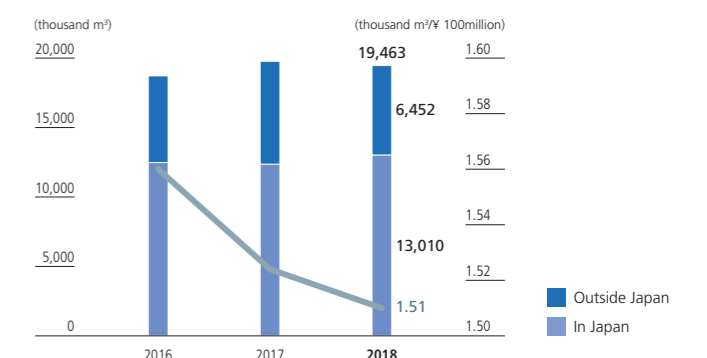
The Otsuka group identifies water resources as a CSR Materiality for its environmental initiatives. Along with evaluating water-related issues and how much water is being used at its key production sites around the world, the Otsuka group also encourages regionally appropriate management and efficient water usage with the goal of conserving and improving water resources.

## Evaluating Water Risks at Production Sites

The Otsuka group has been conducting water risk assessment and evaluation at its production sites using the water risk evaluation tool "Aqueduct," developed by the World Resources Institute (WRI) since 2017, to understand and reduce the impact on its water-related business activities.

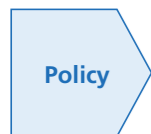
\*Calculated for Otsuka group consolidated subsidiaries and companies included in the top 95% energy-derived CO<sub>2</sub> emission producers

### Water usage and water use efficiency\*





# Governance



In addition to improving management soundness, we work to improve our corporate ethics and work on appropriate risk management.

## Corporate Governance

### Basic Position on Corporate Governance

Otsuka Holdings is committed to promoting sustainable increase of its corporate value over the medium- to long-term by realizing its corporate philosophy: “Otsuka-people creating new products for better health worldwide”. To meet this commitment, it adopts a basic policy of making transparent, fair and timely decisions, and fulfilling its corporate social responsibility by living up to the expectations of all stakeholders, including customers,

business partners, employees, local communities, and shareholders, through ongoing dialogue. The Company articulates its basic approach to corporate governance in its Corporate Governance Guidelines.

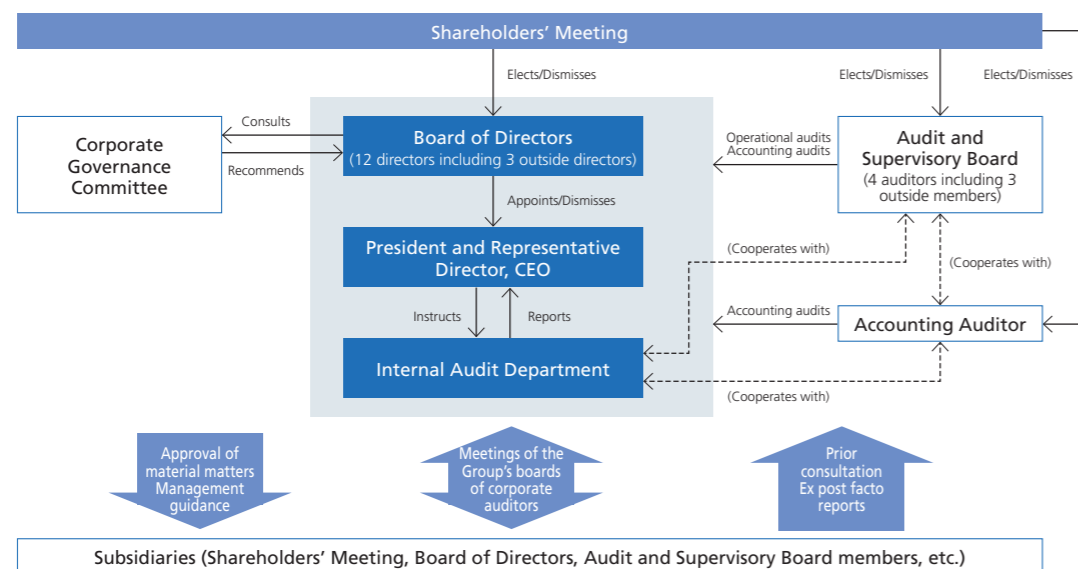
Corporate Governance Guidelines  
<https://www.otsuka.com/en/company/governance/pdf/guideline.pdf>

## Overview of Corporate Governance Structure

The Board of Directors, which also includes Outside Directors, advances the execution of management plans, supervises the Company’s management, and also assumes roles and responsibilities to enhance the profitability and capital investment efficiency in order to promote the sustainable growth of the Company and the increase of corporate value over the medium- to long-term. The Company secures its soundness and establishes the solid corporate governance structure living up to social expectations by ensuring that the Audit & Supervisory Board and its members, which are independent from the Board of Directors, can audit the Directors’ performance of their duties in collaboration with the Accounting Auditor, as well as the Internal Audit Department.

### ■ Governance System – Quick Reference (as of March 28, 2019)

Form of organization	Company with an Audit & Supervisory Board
Board of Directors	12
of which outside directors	3 (independent directors)
Term of directors	One year
Audit & Supervisory Board members	4
of which outside Audit & Supervisory Board members	3 (independent directors)
Accounting auditor	Deloitte Touche Tohmatsu LLC



### ■ Initiatives to Strengthen Corporate Governance

2008	<ul style="list-style-type: none"> <li>Establishment of Otsuka Holdings Co., Ltd.</li> <li>Term of directors set at one year</li> <li>Decision not to adopt a directors' retirement benefits system</li> <li>Corporate officer system adopted</li> <li>Two outside Audit &amp; Supervisory Board members</li> </ul>
2010	<ul style="list-style-type: none"> <li>Three outside Audit &amp; Supervisory Board members</li> <li>Stock options as performance-linked remuneration introduced</li> <li>Stock publicly listed in December</li> </ul>
2011	<ul style="list-style-type: none"> <li>First Medium-Term Management Plan announced</li> </ul>
2013	<ul style="list-style-type: none"> <li>Two outside directors; three outside Audit &amp; Supervisory Board members</li> </ul>
2014	<ul style="list-style-type: none"> <li>Second Medium-Term Management Plan announced</li> <li>Three outside directors; two outside Audit &amp; Supervisory Board members</li> <li>Otsuka Group Global Code of Business Ethics established</li> </ul>
2015	<ul style="list-style-type: none"> <li>Corporate Governance Guidelines established</li> <li>Internal Whistleblowing System established externally (Otsuka Holdings and major group companies)</li> </ul>
2016	<ul style="list-style-type: none"> <li>Three outside directors; three outside Audit &amp; Supervisory Board members</li> <li>Effectiveness of Board of Directors evaluated</li> <li>Stock options conditional on progress with the medium-term management plan introduced</li> </ul>
2017	<ul style="list-style-type: none"> <li>Corporate Governance Guidelines revised</li> <li>Corporate Governance Committee established</li> <li>Effectiveness of Board of Directors evaluated based on questionnaire completed by all directors and Audit &amp; Supervisory Board members</li> <li>Reporting meetings held for outside directors and outside Audit &amp; Supervisory Board members to improve their understanding of the group's management and business</li> </ul>
2018	<ul style="list-style-type: none"> <li>Two female directors</li> <li>Corporate Governance Guidelines revised</li> </ul>
2019	<ul style="list-style-type: none"> <li>Restricted stock compensation plan introduced</li> </ul>

### a) Corporate organization

As a company that adopts the statutory auditor system, the Company has the Board of Directors, the Audit & Supervisory Board, and also engages an accounting auditor. The Articles of Incorporation stipulate that the number of directors shall not exceed 18, and that the number of Audit & Supervisory Board members shall not exceed five.

### b) The Board of Directors

The Board of Directors convenes once a month regularly and holds extraordinary meetings as necessary to make important business decisions and supervise the execution of operations.

### c) Director selection criteria

The Company aims to become “an indispensable contributor to people’s health worldwide” by targeting sustained growth and enhanced corporate value over the medium to long term. To help achieve this goal and also ensure diversity among directors overall, the Company appoints adequate people as directors—people with insight, advanced expertise, and extensive experience conducive to realizing and maintaining appropriate and effective corporate governance. Particularly for internal directors, we comprehensively evaluate the experience, expertise, insights, and other attributes of candidates to ensure that they have the qualities required for implementing the group’s corporate philosophy, Code of Business Ethics, and corporate strategies.

### d) Corporate Governance Committee

In seeking to increase management’s transparency and objectivity, the Company established Corporate Governance Committee in February 2017. As an advisory body to the Board of Directors, the Committee discusses and deliberates the nomination of directors and Audit & Supervisory Board members, the structure

and levels of director remuneration, and other corporate governance issues, and then reports to the Board of Directors. The Committee consists of the CEO, the director in charge of administration, and all outside directors (currently three). The CEO serves as chair of the Committee.

### e) Audit & Supervisory Board member and Audit & Supervisory Board

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 performance of duties by directors. Audits performed by Audit & Supervisory Board are at the core of this process. In striving to improve the effectiveness of audits, Audit & Supervisory Board members also share information and exchange opinions as appropriate with relevant departments, such as Internal Audit Department, Internal Control Department, Administration Department, and Finance and Accounting Department, as well as accounting auditor.

### f) Evaluation of effectiveness of Board of Directors

From January through February every year, the Company conducts a questionnaire survey of all the directors and Audit & Supervisory Board members. Based on the outcomes of the survey, the Company performs an examination and evaluation at the Board of Directors meeting in March following a review by a company attorney.

[ Summary of evaluation in fiscal 2018 ]

The results of the analysis and evaluation of the overall effectiveness of the Board of Directors in fiscal 2018 are summarized below.

1. While some Board members expressed the opinion that collaboration with outside directors and the Audit & Supervisory Board needs to be enhanced, it was confirmed that meetings between the Audit & Supervisory Board and outside directors, as well as opportunities for exchanging opinions with management and outside directors are held regularly through which will serve to further improve communication up ahead.
2. As a result of revising how information is provided to board members, improvements regarding how meetings of the Board of Directors are managed were assessed favorably. It was confirmed that deliberations at meetings will be further enhanced up ahead by taking into account the opinions of Board members.
3. It was confirmed that the system for monitoring the execution of corporate strategies in each business needs to be further enhanced, even though some improvements have been made. While we believe these assessments indicate that the Board of Directors is functioning properly in terms of effectiveness, we will strive to make improvements regarding the issues highlighted in the evaluation and examination, increase the Board’s effectiveness, and make every effort to further deepen corporate governance at the Company.

**g) Independent directors / auditors**

When selecting outside directors and outside Audit & Supervisory Board members, the Company looks for individuals with a great deal of knowledge and extensive experience in various fields. The Company requires that candidates have the ability to adequately exercise management oversight functions through fair and objective monitoring, supervision, and auditing of management from a neutral and objective viewpoint. In addition to requiring that outside directors have not been involved in business execution at

the Otsuka group of companies in the past, we have established independence standards for outside directors in order to ensure their independence. These standards are set out in our Corporate Governance Guidelines. They also apply to outside Audit & Supervisory Board members. Furthermore, given that all outside directors and outside Audit & Supervisory Board members satisfy requirements of independent directors/auditors prescribed by the Tokyo Stock Exchange (TSE), the Company has registered them as such with the TSE.

**■ Rationale for selection of outside directors and auditors**

	Name	Rationale for selection	No. of times attended in FY2018	
			Board of Directors meeting	Audit & Supervisory Board meeting
Outside directors	Yukio Matsutani	Mr. Matsutani has been giving effective advice to the Company's managers from a neutral and expert perspective as an outside director, with his abundant experience and extensive knowledge in the medical welfare field, as well as his expertise in the healthcare industry. Since there is no risk of conflict of interest vis-à-vis general shareholders, moreover, the Company believes Mr. Matsutani to be suitable as an independent director.	13/13	—
	Ko Sekiguchi	The Company anticipates that, given his abundant experience and extensive knowledge as a corporate manager, as well as his expertise in the pharmaceutical industry, Mr. Sekiguchi will be able to give effective advice as appropriate to the Company's managers from a neutral and expert perspective as an outside director. Since there is no risk of conflict of interest vis-à-vis general shareholders, moreover, the Company believes Mr. Sekiguchi to be suitable as an independent director.	10/10	—
	Yoshihisa Aoki*	The Company anticipates that, given his abundant experience, track record, and insight as a corporate manager, as well as his ample experience, expertise, and network in the food industry, Mr. Aoki will be able to provide beneficial and shrewd advice to the Company's management from an objective and expert perspective as an outside director. As there is no risk of conflicts of interest with general shareholders, the Company believes Mr. Aoki to be suitable as an independent director.	—	—
Outside Audit & Supervisory Board members	Hiroshi Sugawara	Mr. Sugawara has specialized knowledge as a certified public accountant, as well as abundant business experience, and the Company has determined that he will be able to use such experience and expertise in audits of the Company. Since there is no risk of conflict of interest vis-à-vis general shareholders, moreover, the Company has designated Mr. Sugawara as an independent audit & supervisory board member.	13/13	16/16
	Yoko Wachi	As an attorney, Ms. Wachi is well-versed in corporate legal affairs, and the Company has determined that she will be able to use such experience and expertise in audits of the Company. Since there is no risk of conflict of interest vis-à-vis general shareholders, moreover, the Company has designated Ms. Wachi as an independent audit & supervisory board member.	13/13	16/16
	Kazuo Takahashi	Mr. Takahashi has held major positions in the IT and internal control departments for many years and has abundant experience in corporate management, and the Company has determined that he will be able to use such experience and expertise in audits of the Company. Since there is no risk of conflict of interest vis-à-vis general shareholders, moreover, the Company has designated Mr. Takahashi as an independent audit & supervisory board member.	10/10	13/13

\*The number of Board of Directors meetings and Audit & Supervisory Board meetings attended by outside director Yoshihisa Aoki is not listed because he was newly appointed at the 111th General Meeting of Shareholders held on March 28, 2019.

**Independence Standards for Outside Directors (Corporate Governance Guidelines 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, in which 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.

**h) 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 with regard to the assets and business in general 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 business execution. The department also shares information and cooperates with Audit & Supervisory Board members and accounting auditor.

**i) Internal Control Department**

The Company's Internal Control Department handles internal controls regarding 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 works in cooperation with the Internal Audit Department to continuously monitor the status of operations, thus establishing a system under which executives can reliably

assess internal controls. Our basic approach to our internal control system and its establishment is described in the corporate governance report submitted to the TSE.

**j) Accounting audit**

Otsuka Holdings has signed an auditing agreement with the auditing firm Deloitte Touche Tohmatsu LLC as accounting auditor to audit the Company's accounts from a fair and impartial stance. The certified public accountants who audited the Company's accounts were Tsutomu Hirose, Koichi Niki, and Ichiro Matsunaga. They were assisted by 10 other certified public accountants and three other people. All of the certified public accountants who audited the Company's accounts have done so continuously for less than seven years, therefore omitted that description.

**k) Succession plan**

In order to identify talented personnel early and systematically develop next-generation executives equipped with qualities and skills required under our corporate philosophy, Otsuka Holdings continuously builds and implements a next-generation executives development program and regularly reports on its progress to the Board of Directors.

Human Resource Development → p.63

**Remuneration for Directors / Auditors**

Remuneration system for directors and auditors is designed so that the Company attracts and retains talented personnel and strongly motivates them to perform their duties, thereby contributing to sustained improvement in the group's earnings and corporate value.

Management Plan, combining multiple conditions of earnings achievement based on the earnings indicators in our 3rd Medium-Term Management Plan.

**a) Director remuneration at the company as a holding company**

Remuneration for directors of Otsuka Holdings, a holding company, consists of fixed remuneration according to title or position, bonuses linked to performance that provide short-term incentives, and stock-based compensation that provides medium- to long-term incentives. Beginning in fiscal 2019, we will be replacing stock options with a restricted stock-based compensation system as an incentive plan to achieve sustained growth in medium- to long-term earnings and corporate value. The restricted stocks issued under this system are part of a compensation system that reflects the attainment of Medium-Term

**b) Remuneration for directors of subsidiaries as operating companies**

Remuneration for directors of subsidiaries as operating companies is determined based on their duties and responsibilities (execution of business based on group strategies formulated by Otsuka Holdings, as well as duties and responsibilities involving the formulation of strategies for the operating company, and strengthening corporate governance) and is not to exceed the cap on director remuneration resolved at the General Meeting of Shareholders. Note that the restricted stock-based compensation system newly implemented in fiscal 2019 will also apply to roughly 40 directors (excluding outside directors) at some of the group's major subsidiaries.

**c) Remuneration for auditors of the Company**

Audit & Supervisory Board members are essentially paid only basic remuneration; there are no variable components based on earnings.

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

Officer category	Total remuneration etc. (¥ million)	Total remuneration, by type (¥ million)			Number of officers who receive basic remuneration
		Basic remuneration	Amount charged as cost of stock options	Bonus	
Directors (excluding outside directors)	350	273	-45	123	8
Audit & Supervisory Board members (excluding outside Audit & Supervisory Board members)	25	25	—	—	2
Outside directors	54	54	—	—	8

**Compliance**

**Basic Policy**

Legal compliance forms the cornerstone of all our business activities. The Otsuka group possesses high ethical standards and we

**Approach**

The Otsuka group has established Otsuka Group Global Code of Business Ethics and we openly publish information about our stance on initiatives in line with this code on our website in the form of a message from the President of Otsuka Holdings. We have also drawn up the Otsuka Group Global Anti-Corruption Policy, which represents our stance on preventing corruption at all of our sites worldwide. Accordingly, we continue to conduct our business activities based on a strong sense of ethics. We hold universal training sessions once or more every year based on the content of the aforementioned code and policy—they are attended by all employees of subsidiaries and we prepare materials in English, Chinese, and Indonesian, in addition to Japanese. Furthermore, details about our training sessions are reported regularly to the Board of Directors of Otsuka Holdings. Internal compliance-related audits are implemented periodically at each group company, the results of which are reported to the Board of Directors. As for initiatives overseas, compliance officers have been appointed at each of our group companies in Asia and

aim to achieve sustained growth along with earning the trust of our customers by conducting our business activities honestly.

regular meetings are held so the progress of initiatives in each country can be shared. A compliance officer from Otsuka Holdings also visits our overseas group companies to gather information and offer suggestions on how improvements may be made. A due diligence policy is also in force at each of our group companies. We conduct due diligence on new business partners for the purpose of assessing risk related to corruption. And at Otsuka Holdings and our leading group companies, we have taken steps to establish internal whistleblowing systems that can be accessed from within the company or from an external location, such as the offices of our attorneys. Our rules allow for whistleblowing not only by full-time employees but also by contract, dispatched, and part-time employees, all of whom can rest assured knowing that information about themselves and their reports are strictly managed to prevent any negative repercussions. Information related to the internal whistleblowing systems at the major group companies is reported regularly at the Board of Directors meetings of Otsuka Holdings.

**Tax Compliance**

**Basic Policy**

The Otsuka group operates in countries around the world and recognizes that the appropriate payment of taxes in accordance with relevant laws and regulations in each country and region

**Approach**

The Otsuka group complies with the aforementioned code of ethics, tax policies, country-specific laws, tax conventions, and

contributes to the local economy in those countries and regions. The Otsuka group fulfills its tax obligations in accordance with the Otsuka Group Global Code of Business Ethics.

international taxation rules, submitting tax declarations correctly, paying corporate tax, and not engaging in transactions designed

to evade the payment of taxes. The group also endeavors to appropriately disclose information and ensure a degree of trans-

parency and trust when dealing with tax authorities worldwide.

**Risk Management**

**Basic Policy**

The Otsuka group carries out risk management under the supervision of top management based on the recognition that pursuing

management efficiency and controlling the risks inherent in its business activities is key if it is to enhance corporate value.

**Risk Management System**

In establishing a risk management system for the Otsuka group, we have put in place Risk Management Policy and set up Risk Management Committee comprising director in charge of administration, President and Representative Director (as chair),

and others. Leveraging the controls put in place by each risk management department, Risk Management Committee assesses and comprehensively manages the risks that jeopardize the enhancement of the group's sustained corporate value.

**Approach**

We individually assess risks in each of our businesses. The risk management officer performs analyses and evaluation, formulates and executes action plans with the aim of meeting objectives and targets for the organization, and periodically implements employee training with reference to events that

could pose a risk within the organization. Training related to topics such as corruption prevention and the protection of human rights based on the Otsuka Group Global Code of Business Ethics is also part of this approach. We also regularly hold drills to prepare for unexpected contingencies like disasters.

**Business Continuity Planning and Management**

The Otsuka group has business continuity plans (BCP) in place to ensure that the group continues to operate as effectively as possible and can maintain a stable supply of products, even when large-scale earthquakes and disasters strike. From the perspective of business continuity management (BCM), Otsuka Holdings and the group companies have jointly constructed a group-wide business continuity framework. We have gradually expanded the scope of this framework since acquiring ISO22301 certification in August 2012 for the production and stable supply of medicinal products, beverages, and foods. We then acquired certification for the stable supply of infusion solutions in April 2015, followed by the stable supply of anticancer drugs in May 2016. The acquisition of ISO22301 certification demonstrates

that from a BCM standpoint, our organization is equipped with infallible business continuity capabilities. Through collaboration mainly between Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, and Otsuka Warehouse, we are making every effort to strengthen our countermeasures and systems so that the Otsuka group as a whole can continue its business activities as best as possible and guarantee stable product supply even during times of disaster. In 2018, our major group companies jointly conducted a desktop simulation drill on the assumption of an earthquake with an epicenter directly below Tokyo. The drill provided an opportunity to test out our collaborative framework based on the topic of ensuring stable product supply.

**Information Security**

In striving to raise the level of, and constantly improve, comprehensive security across the group, we set up Otsuka Group Information Security Committee to facilitate the sharing of up-to-date security information and the examination of specific security measures. In order to counter the risk of cyber-attacks, the Otsuka group employs a number of measures, such as arranging system security audits by external specialists, diagnosing website vulnerabilities, conducting drills related to targeted email attacks, and monitoring posts on social media. In addition, the group conducts regular emergency drills with a focus on core systems

which construct data. The Otsuka group has established a management system to protect sensitive personal information of its customers and has acquired personal information protection management system (PrivacyMark) certification and information security management system (ISMS) certification for its businesses where appropriate. Otsuka also established its EU General Data Protection Regulation Compliance Policy in 2017 concerning General Data Protection Regulation (GDPR) as part of group-wide initiatives on information security.



# Directors, Audit & Supervisory Board Members

(as of March 28, 2019)



From left: Noriko Tojo, Yoshihisa Aoki, Sadanobu Tobe, Yukio Matsutani, Yoshiro Matsuo, Ko Sekiguchi, Ichiro Otsuka



Tatsuo Higuchi, Yozo Toba, Yuko Makino, Hiroshi Sugawara, Shuichi Takagi, Yoko Wachi, Atsumasa Makise, Kazuo Takahashi, Masayuki Kobayashi

## Directors

### Chairman and Representative Director Ichiro Otsuka

Apr. 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.  
Dec. 2001 Executive Director, Research and Development, Otsuka Pharmaceutical Factory, Inc.  
May 2002 Representative Director, Otsuka Pharmaceutical Factory, Inc.  
Dec. 2003 Executive Deputy President and Representative Director, Otsuka Pharmaceutical Factory, Inc.  
Dec. 2004 President and Representative Director, Otsuka Pharmaceutical Factory, Inc.  
July 2008 Executive Director, Otsuka Holdings Co., Ltd.  
June 2010 Executive Deputy 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.  
Mar. 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)

### Executive Director, CFO Yuko Makino

Apr. 1982 Joined Otsuka Pharmaceutical Co., Ltd.  
Apr. 1996 Joined Baxter Limited  
Apr. 2000 Joined Otsuka Pharmaceutical Co., Ltd.  
Mar. 2015 Director of the Corporate Finance & Accounting Department, Otsuka Holdings Co., Ltd.  
Sept. 2016 Vice President, Director of the Corporate Finance & Accounting Department, Otsuka Holdings Co., Ltd.  
Vice President, Director of Accounting Department, Otsuka Pharmaceutical Co., Ltd.  
Apr. 2017 Vice President, Director of the Tax Department, Otsuka Holdings Co., Ltd.  
Vice President, Director of the Finance & Accounting Department, Otsuka Pharmaceutical Co., Ltd.  
Mar. 2018 Executive Director, Corporate Finance, Otsuka Holdings Co., Ltd.  
Mar. 2019 Executive Director, CFO, Otsuka Holdings Co., Ltd. (Current Position)

### Executive Director Masayuki Kobayashi

Oct. 1993 Joined Taiho Pharmaceutical Co., Ltd.  
Aug. 2002 President, Taiho Pharma USA, Inc. (present day TAIHO ONCOLOGY, INC.)  
Sept. 2003 Executive Director, Taiho Pharmaceutical Co., Ltd.  
Apr. 2010 President and CEO, Otsuka America, Inc.  
Apr. 2012 President and Representative Director, Taiho Pharmaceutical Co., Ltd. (Current Position)  
Executive Director, Taiho Pharma USA, Inc.  
Apr. 2014 Chairman, TAIHO ONCOLOGY, INC. (Current Position)  
Mar. 2017 Executive Director, Otsuka Holdings Co., Ltd. (Current Position)

### President and Representative Director, CEO Tatsuo Higuchi

Mar. 1977 Joined Otsuka Pharmaceutical Co., Ltd.  
June 1998 Senior Managing Director, Otsuka Pharmaceutical Co., Ltd. (Pharmavite)  
Nov. 1998 Executive Deputy 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, CEO, Otsuka Holdings Co., Ltd. (Current Position)  
Dec. 2011 Executive Director, Otsuka Chemical Co., Ltd.  
Feb. 2015 President and Representative Director, Otsuka Pharmaceutical Co., Ltd. (Current Position)

### Executive Director Sadanobu Tobe

Apr. 1976 Senior Managing Director and Representative Director, Shinko Foods Co., Ltd. (present day Otsuka Foods Co., Ltd.)  
July 1993 Executive Deputy President and Representative Director, Otsuka Foods Co., Ltd.  
Nov. 2004 Executive Deputy 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.  
Nov. 2013 President and Representative Director, Otsuka Foods Co., Ltd.  
June 2014 Executive Director, Otsuka Holdings Co., Ltd. (Current Position)  
Mar. 2018 Chairman, Otsuka Foods Co., Ltd.  
Mar. 2019 Executive Director, Otsuka Foods Co., Ltd. (Current Position)

### Executive Director Noriko Tojo

Apr. 1987 Joined Goldman Sachs (Japan) Corporation  
Aug. 1991 Joined Shearson Lehman Brothers Holdings Inc.  
July 2002 Engagement Manager, McKinsey & Company, Japan Office  
June 2006 Director, Intel Capital Japan, Intel Corporation  
Aug. 2008 Managing Director, Corporate Development, Otsuka Holdings Co., Ltd.  
Feb. 2011 Executive Director, Otsuka Medical Devices Co., Ltd.  
Apr. 2012 President and CEO, Otsuka America, Inc.  
Aug. 2015 Executive Director and CEO, Pharmavite LLC  
Jan. 2017 President and Representative Director, Otsuka Medical Devices Co., Ltd. (Current Position)  
May 2017 Executive Director, Otsuka America, Inc.  
Aug. 2017 Chairman, Pharmavite LLC  
Mar. 2018 Executive Director, Otsuka Holdings Co., Ltd. (Current Position)

### Senior Managing Director Yoshiro Matsuo

Apr. 1985 Joined Otsuka Pharmaceutical Co., Ltd.  
Jan. 2003 Vice President, Associate General Manager of the General Affairs Department, Otsuka Pharmaceutical Co., Ltd.  
June 2006 Vice President, General Manager of the General Affairs Department, Otsuka Pharmaceutical Co., Ltd.  
Nov. 2007 Senior Vice President, 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.  
Mar. 2016 Senior Managing Director, Corporate Administration, Otsuka Holdings Co., Ltd.  
Jan. 2017 Executive Director, Otsuka Medical Devices Co., Ltd. (Current Position)  
Mar. 2019 Senior Managing Director, Otsuka Holdings Co., Ltd. (Current Position)

### Executive Director Atsumasa Makise

Dec. 1987 Joined Otsuka Pharmaceutical Co., Ltd.  
June 2002 Vice President, Director of ODPPI Division, Otsuka Pharmaceutical Co., Ltd.  
June 2003 Vice President, 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, Corporate Finance, Otsuka Holdings Co., Ltd.  
May 2009 Chairman and CEO, Otsuka America Inc.  
Apr. 2010 Chairman, Otsuka America Inc.  
Mar. 2017 Executive Director, Otsuka Foods Co., Ltd.  
Mar. 2018 President and Representative Director, Otsuka Foods Co., Ltd. (Current Position)  
Executive Director, Otsuka Holdings Co., Ltd. (Current Position)

### Executive Director, Business Portfolio Management Shuichi Takagi

Apr. 1989 Joined TOBISHIMA CORPORATION  
Sept. 1995 Joined Otsuka Pharmaceutical Co., Ltd.  
Aug. 2002 Finance Department of OIAA Division, Otsuka Pharmaceutical Co., Ltd.  
July 2003 Corporate Finance & Accounting Department, Otsuka Pharmaceutical Co., Ltd.  
Mar. 2015 Vice President responsible for India Business, Otsuka Pharmaceutical Factory, Inc.  
May 2015 CEO, Claris Otsuka Private Limited (present day Otsuka Pharmaceutical India Private Limited)  
Jan. 2019 Senior Vice President, President's Office, Otsuka Holdings Co., Ltd.  
Mar. 2019 Executive Director, Business Portfolio Management, Otsuka Holdings Co., Ltd. (Current Position)

### Outside Director Yukio Matsutani

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

### Outside Director Ko Sekiguchi

Apr. 1973 Joined Mitsubishi Corporation  
May 1990 Joined The Boston Consulting Group  
Jan. 1996 General Manager of Sterrad Business Division, Johnson & Johnson Medical K. K. (present day Johnson & Johnson K. K. Medical Company)  
Nov. 1998 President and Representative Director, Janssen Kyowa Co., Ltd. (present day Janssen Pharmaceutical K. K.)  
July 2009 Chairman and Director, Janssen Kyowa Co., Ltd.  
Oct. 2009 Supreme Advisor, Janssen Kyowa Co., Ltd.  
Jan. 2011 Representative Director, DIA Japan (present day SH DIA Japan)  
Apr. 2012 Outside Director, N.I.C. Corporation (present day Solasto Corporation) (Current Position)  
Mar. 2014 Outside Director, Kenedix, Inc.  
Mar. 2018 Outside Director, Otsuka Holdings Co., Ltd. (Current Position)

### Outside Director Yoshihisa Aoki

Apr. 1974 Joined ITOCHU Corporation  
June 2003 Executive Officer, ITOCHU Corporation  
Apr. 2009 Managing Executive Officer, President, Food Company, ITOCHU Corporation  
Apr. 2010 Member of the Board, Senior Managing Executive Officer, President, Food Company, ITOCHU Corporation  
Mar. 2017 Administrative Officer, ITOCHU Corporation (Current Position)  
June 2017 Outside Director, ARATA CORPORATION (Current Position)  
Mar. 2019 Outside Director, Otsuka Holdings Co., Ltd. (Current Position)

## Audit & Supervisory Board Members

### Standing Audit & Supervisory Board Member Yozo Toba

Apr. 1979 Joined Otsuka Chemical Co., Ltd.  
Jan. 1995 Director, Information Center, Otsuka Chemical Co., Ltd.  
Jan. 2006 CFO, Trocenen GmbH  
May 2009 Operating Officer, Information System Department, Otsuka Chemical Holdings Co., Ltd. (present day Otsuka Chemical Co., Ltd.)  
June 2009 Corporate Officer, Director of IT, Corporate Finance & Accounting Department, Otsuka Holdings Co., Ltd.  
Dec. 2011 Executive Director, Corporate Administration, Accounting and IT, Otsuka Chemical Co., Ltd.  
Mar. 2015 Executive Vice President, Corporate Finance & Accounting & Corporate Service Department, Otsuka Holdings Co., Ltd.  
Mar. 2018 Standing Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

### Outside Audit & Supervisory Board Member Hiroshi Sugawara

Oct. 1997 Joined Chuo Audit Corporation  
Oct. 2000 Joined Deloitte Touche Tohmatsu (present day Deloitte Touche Tohmatsu LLC)  
Feb. 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.  
Oct. 2013 Outside Director, NIPPON PARKING DEVELOPMENT Co., Ltd.  
Mar. 2016 Audit & Supervisory Board Member, Otsuka Pharmaceutical Co., Ltd. (Current Position)

### Outside Audit & Supervisory Board Member Yoko Wachi

Apr. 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)  
Mar. 2016 Outside Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

### Outside Audit & Supervisory Board Member Kazuo Takahashi

Apr. 1975 Joined EBARA-UDYLITE CO., LTD. (present day ICU CORPORATION)  
Mar. 1986 Executive Director, Strategic Planning, RA Institute Co., Ltd.  
Nov. 1992 Executive Director, General Manager of the System Division, Sunkus & Associates, Inc. (Current Position)  
Oct. 2004 Executive Director, Head of the Information System Division, Circle K Sunkus Co., Ltd.  
May 2006 Executive Director, Chief of the Management Strategy Office, the Customer & Franchisee Relations Office, and the Internal Control & Environmental Management Office, Circle K Sunkus Co., Ltd.  
May 2008 Executive Director, Head of Area Franchise, Circle K Sunkus Co., Ltd.  
May 2010 Executive Director, Head of Information Systems Division, Circle K Sunkus Co., Ltd.  
Mar. 2018 Outside Audit & Supervisory Board Member, Otsuka Holdings Co., Ltd. (Current Position)

## Main Data

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

Item*1		Billions of Yen					Billions of Yen				Millions of U.S. Dollars **4
		J-GAAP			J-GAAP		IFRS				IFRS
		2011.3	2012.3	2013.3	2014.3	2014.12**3	2015.12	2016.12	2017.12	2018.12	2018.12
<b>Results of Operations</b>	Revenue	¥ 1,127.6	¥ 1,154.6	¥ 1,218.1	¥ 1,452.8	¥ 1,224.3	¥ 1,427.4	¥ 1,195.5	¥ 1,240.0	¥ 1,292.0	\$ 11,639
	Selling, general and administrative expenses**2	457.6	457.4	462.2	563.4	508.6	636.4	535.9	558.7	564.4	5,084
	Research and development expenses	164.7	159.2	192.4	249.0	172.9	202.7	168.8	175.6	216.1	1,947
	R&D ratio (%)	14.6	13.8	15.8	17.1	14.1	14.2	14.1	14.2	16.7	—
	Operating profit	126.3	148.7	169.7	198.7	196.5	148.9	101.1	104.2	108.3	976
	Operating profit margin (%)	11.2	12.9	13.9	13.7	16.1	10.4	8.5	8.4	8.4	—
	Profit attributable to owners of the Company	82.4	92.2	122.4	151.0	143.1	102.0	92.6	112.5	82.5	743
<b>Financial Position</b>	Total assets	¥ 1,589.7	¥ 1,666.8	¥ 1,779.2	¥ 2,028.4	¥ 2,178.2	¥ 2,575.3	¥ 2,478.3	¥ 2,480.3	¥ 2,476.6	\$ 22,312
	Total equity	1,163.3	1,222.8	1,325.1	1,510.8	1,658.6	1,727.4	1,738.4	1,822.0	1,732.3	15,606
	Ratio of equity attributable to owners of the Company to total assets (%)	72.4	72.5	73.7	73.2	74.7	66.0	69.0	72.3	68.8	—
	ROE (%)	7.9	7.8	9.7	10.8	9.2	6.1	5.4	6.4	4.7	—
<b>Cash Flows</b>	Net cash flows from operating activities	¥ 87.7	¥ 147.6	¥ 119.3	¥ 226.5	¥ 88.5	¥ 257.9	¥ 142.0	¥ 102.8	¥ 135.8	\$ 1,224
	Net cash flows from investing activities	(131.5)	(107.6)	(91.2)	(108.5)	(28.7)	(422.6)	(135.1)	(40.1)	(93.3)	(841)
	Free cash flows	(43.8)	40.0	28.1	117.9	59.9	(164.7)	6.9	62.8	42.5	383
<b>Dividends</b>	Annual dividend per share (Yen)	¥ 28	¥ 45	¥ 58	¥ 65	¥ 75	¥ 100	¥ 100	¥ 100	¥ 100	\$ 0.90
	Dividend pay-out ratio (%)	17.3	27.2	26.1	23.4	28.4	53.1	58.5	48.2	65.7	—
<b>Common Stock/ Stock Price</b>	Number of shares outstanding at year-end (thousand shares)	557,836	557,836	557,836	557,836	557,836	557,836	557,836	557,836	557,836	—
	Stock price at year-end (Yen)	¥ 2,055	¥ 2,450	¥ 3,300	¥ 3,087	¥ 3,617	¥ 4,317	¥ 5,093	¥ 4,948	¥ 4,493	\$ 40.48
<b>Number of Employees *5</b>	Total (persons)	25,188	24,595	25,330	28,288	29,482	31,940	31,787	32,817	32,935	
	Japan (persons)	14,030	13,808	13,732	14,116	14,285	14,082	13,909	13,880	13,757	
	Outside Japan (persons)	11,158	10,787	11,598	14,172	15,197	17,858	17,878	18,937	19,178	
<b>Female Manager Ratio *6</b>	Number of female managers (persons)			187	202	226	248	269	270	280	
	Female manager ratio (%)			4.8	5.3	6.1	7.0	7.7	7.8	8.1	
<b>Environmental Data *7</b>	Total CO <sub>2</sub> emissions*8 (thousand tons-CO <sub>2</sub> )							801	818	842	
	Japan (%)							42.8	39.8	38.5	
	Outside Japan (%)							57.2	60.2	61.5	
	CO <sub>2</sub> emissions per sales (ton/¥ million)							0.67	0.66		
	Water usage*8 (thousand m <sup>3</sup> )							18,721	19,768	19,463	
	Resource recycling rate*9 (%)							98.3	98.9	99.5	

\*1 Item names according to IFRS.

\*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 111.00=US\$1, the approximate exchange rate on December 31, 2018.

\*5 Number of employees at Otsuka Holdings and its 162 subsidiaries (as of December 31, 2018).

\*6 6 companies (non-consolidated): Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, Otsuka Warehouse, and Otsuka Foods

\*7 Environmental data is limited to the past four years due to a change in collation criteria from 2016.

\*8 Calculated for the consolidated subsidiaries of the Otsuka group, and the companies that constitute the top 95% or more of CO<sub>2</sub> emissions originating from energy.

\*9 Figures of 14 major consolidated subsidiaries in Japan.

# Management Discussion and Analysis of Consolidated Financial Results for Fiscal 2018

## Market environment

The environment surrounding the healthcare industry is currently experiencing a period of change. In particular, an aging society, the introduction of expensive drugs, and outbreaks of infectious diseases are contributing to ever-increasing health care budgets, making governments of Japan, the United States and those in the Europe become more aware of costs for medical treatments. Faced with limited financial resources, medical guidelines are caught in the balance between the costs and benefits of treatments, while the penetration of generic drugs and reforms to the drug pricing system are continuing to progress, and expensive medical treatments and new technologies are emerging as well.

Under these circumstances, needs are steadily increasing for daily measures for disease prevention and balanced life plans that include nutrition, in addition to exercise and rest.

The Otsuka group's operations encompass two core businesses: the pharmaceutical business, which provides comprehensive health support from diagnosis to disease treatment, and the nutraceutical business, which assists people in maintaining and improving their day-to-day health. In response to the growing awareness of health, we are reconfirming our strong belief in the importance of total health care including disease prevention.

## Status of revenues

During the fiscal year that ended December 31, 2018, the Otsuka group recorded consolidated revenues of 1,291,981 million yen (up 4.2% from the previous fiscal year), with operating profit of 108,304 million yen (up 4.0%), profit for the year of 85,395 million yen (down 25.3%) and profit attributable to owners of the Company of 82,492 million yen (down 26.7%).

Strong growth of global products and a new product lineup contributed favorably to increased revenues. The group achieved a growth in operating profit, even after actively investing in R&D. Profit attributable to owners of the Company decreased from the previous fiscal year, due mainly to the 2017 tax reform in the U.S., the transient impact of which reversed income tax expenses into profits. Excluding this impact, profit attributable to owners of the Company for the current fiscal year would be on par with those of the previous fiscal year.

During the current fiscal year, 17,971 million yen was recognized as other income, which is related to a transaction in which the group acquired the remaining shares of ReCor Medical Inc., transformed the company into a wholly owned subsidiary, and reevaluated its existing shareholding and contractual rights with ReCor Medical, Inc. in accordance with the IFRS.

In addition, an impairment loss of 23,208 million yen on intangible assets (in-process research and development) was recorded as R&D expenses, as a result of revising future profitability projections for centanafadine (development code:

EB-1020) and guadecitabine (development code: SGI-110), which are currently being developed for the treatment of attention deficit hyperactivity disorder (ADHD) and acute myeloid leukemia (AML), respectively.

Selling, general, and administrative expenses for the current fiscal year included an impairment loss of 11,533 million yen on intangible assets (trademarks, marketing rights, etc.), due to termination of the license agreement for *ONZETRA Xsail* (generic name: sumatriptan). In addition, in this fiscal year Avanir Pharmaceuticals, Inc. (California-based subsidiary of the Otsuka group) has reached an agreement in principle to resolve the United States Department of Justice's investigation related to certain of Avanir's past sales and marketing practices for its product *NUDEXTA*®. The agreement in principle between Avanir and the United States is contingent upon the parties' negotiation and execution of civil, criminal and administrative agreements. We estimated that fines, damages, disgorgement, restitution, legal fees and interest charges may total approximately \$120 million, part of which had been accrued in the previous fiscal year, so in this fiscal year we accrued the remaining ¥10,064 million in "Selling, general and administrative expenses."

## Financial position

### Assets

Total assets as of December 31, 2018 were 2,476,634 million yen, a decrease of 3,621 million yen compared to 2,480,256 million yen at the end of the previous fiscal year. Current assets decreased by 77,840 million yen, while non-current assets increased by 74,218 million yen. Both the decrease in current assets and the increase in non-current assets were due mainly to the fact that the Group used cash-on-hand to finance the acquisition of the remaining shares of ReCor Medical, Inc. and the acquisition of Visterra, Inc.

#### (Current assets)

Total current assets as of December 31, 2018 amounted to 933,102 million yen, a decrease of 77,840 million yen compared to 1,010,942 million yen at the end of the previous fiscal year. This decrease was mainly due to decreases in cash and cash equivalents of 51,590 million yen, and other financial assets of 49,769 million yen, which offset increases in trade and other receivables of 14,600 million yen, and inventories of 12,589 million yen.

#### (Non-current assets)

Total non-current assets as of December 31, 2018 were 1,543,532 million yen, an increase of 74,218 million yen compared to 1,469,313 million yen at the end of the previous fiscal

year. This increase was mainly due to increases in property, plant and equipment of 11,109 million yen, goodwill of 34,633 million yen, intangible assets of 28,080 million yen, and deferred tax assets of 21,448 million yen, while there was also a decrease in other financial assets of 20,951 million yen.

### Liabilities

Total liabilities as of December 31, 2018 were 744,368 million yen, an increase of 86,061 million yen compared to 658,306 million yen at the end of the previous fiscal year. This increase was mainly due to 98,054 million yen in current and non-current contract liabilities resulting from the application of IFRS 15 from fiscal 2018, while there was also a 35,548 million yen decrease in current and non-current bonds and borrowings due to the scheduled payment of borrowings for the acquisition of Avanir Pharmaceuticals, Inc.

#### (Current liabilities)

Total current liabilities as of December 31, 2018 were 427,502 million yen, an increase of 41,036 million yen compared to 386,465 million yen at the end of the previous fiscal year. This increase was mainly due to increases in trade and other payables of 10,956 million yen, contract liabilities of 10,809 million yen accompanying the application of IFRS 15 from fiscal 2018, and other current liabilities of 16,793 million yen.

#### (Non-current liabilities)

Total non-current liabilities as of December 31, 2018 were 316,865 million yen, an increase of 45,025 million yen compared to 271,840 million yen at the end of the previous fiscal year. This increase was mainly due to an increase in contract liabilities of 87,245 million yen due to the application of IFRS 15 from fiscal 2018, while there was also a decrease in bonds and borrowings of 36,988 million yen.

## Equity

Total equity as of December 31, 2018 was 1,732,266 million yen, a decrease of 89,683 million yen compared to 1,821,950 million yen at the end of the previous fiscal year. This decrease was mainly due to a 37,039 million yen decrease in retained earnings as a result of 54,184 million yen in payment of dividends, 82,492 million yen in profit attributable to owners of the Company, a 70,242 million yen impact due to the application of IFRS 15, and a 52,011 million yen decrease in other components of equity, due to stock market and exchange rate fluctuations.

## Status of cash flows

Cash and cash equivalents as of December 31, 2018 decreased by 51,590 million yen to 285,022 million yen, from the end of

the previous fiscal year. Net cash provided by operating activities was 135,821 million yen in fiscal 2018. Net cash used in investing activities was 93,341 million yen, due to investments made for the future, including acquisition of the remaining shares of ReCor Medical, Inc. and acquisition of Visterra, Inc. Net cash used in financing activities was 89,198 million yen, as a result of dividend payments of 100 yen per share to shareholders (54,184 million yen in total) and repayments of non-current borrowings of 41,755 million yen. As a result, the total amount of cash outflows from investing and financing activities exceeded operating cash inflows.

The total amount of bonds and borrowings as of December 31, 2018 was 205,885 million yen, which was exceeded by total cash and cash equivalents. Therefore, the group has maintained its own financial soundness.

The status of the Group's cash flows during fiscal 2018, along with the contributing factors, is as follows.

### Cash flows from operating activities

Net cash provided by operating activities in fiscal 2018 amounted to 135,821 million yen. The contributing factors were 109,497 million yen in profit before taxes, 59,275 million yen in depreciation and amortization expenses, 34,742 million yen in impairment loss and reversal of impairment loss, 16,508 million yen in share of profit of associates, 20,468 million yen in increase in trade and other receivables, and 29,589 million yen in income taxes paid.

### Cash flows from investing activities

Net cash used in investing activities in fiscal 2018 amounted to 93,341 million yen. The main investing activities included 57,075 million yen in payments for acquisition of property, plant and equipment, 16,533 million yen in payments for acquisition of intangible assets, 33,846 million yen in proceeds from sales and redemption of investments, 32,136 million yen in payments for acquisition of investments, 68,101 million yen in payments for acquisition of subsidiaries, and 47,287 million yen in decrease in time deposits. The payments for acquisition of subsidiaries were primarily for the acquisition of the remaining shares of ReCor Medical, Inc. and the acquisition of Visterra, Inc.

### Cash flows from financing activities

Net cash used in financing activities in fiscal 2018 amounted to 89,198 million yen. The main financing activities included 6,544 million yen in proceeds from non-current borrowings, 41,755 million yen in repayments of non-current borrowings, and 55,295 million yen in dividends paid.

# Consolidated Financial Statements

Otsuka Holdings and its Subsidiaries for the year ended December 31, 2018

## Consolidated Statement of Financial Position

Assets	Billions of Yen		Millions of U.S. Dollars*
	2017.12	2018.12	2018.12
<b>Current assets</b>			
Cash and cash equivalents	¥ 336.6	¥ 285.0	\$ 2,568
Trade and other receivables	363.9	378.5	3,410
Inventories	144.5	157.1	1,416
Income taxes receivable	11.5	9.2	83
Other financial assets	116.4	66.6	600
Other current assets	37.5	36.6	329
Subtotal	1,010.5	933.1	8,406
Assets held for sale	0.5	0	0
<b>Total current assets</b>	<b>1,010.9</b>	<b>933.1</b>	<b>8,406</b>
<b>Non-current assets</b>			
Property, plant and equipment	382.5	393.6	3,546
Goodwill	249.5	284.1	2,559
Intangible assets	455.9	483.9	4,360
Investments in associates	188.2	189.6	1,708
Other financial assets	176.1	155.2	1,398
Deferred tax assets	7	28.4	256
Other non-current assets	10.2	8.7	78
<b>Total non-current assets</b>	<b>1,469.3</b>	<b>1,543.5</b>	<b>13,906</b>
<b>Total assets</b>	<b>¥ 2,480.3</b>	<b>¥ 2,476.6</b>	<b>\$ 22,312</b>

Liabilities and equity	Billions of Yen		Millions of U.S. Dollars*
	2017.12	2018.12	2018.12
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	¥ 159.9	¥ 170.9	\$ 1,539
Bonds and borrowings	64.5	65.9	594
Other financial liabilities	2.3	4.2	38
Income taxes payable	8.0	7.2	65
Contract liabilities	—	10.8	97
Other current liabilities	151.7	168.5	1,518
Subtotal	386.5	427.5	3,851
Liabilities directly associated with assets held for sale	0	0	0
<b>Total current liabilities</b>	<b>386.5</b>	<b>427.5</b>	<b>3,851</b>
<b>Non-current liabilities</b>			
Bonds and borrowings	177.0	140.0	1,261
Other financial liabilities	19.0	22.8	206
Net defined benefit liabilities	14.7	18.3	165
Provisions	3.7	0.6	6
Contract liabilities	—	87.2	786
Deferred tax liabilities	44.7	35.6	320
Other non-current liabilities	12.8	12.3	111
<b>Total non-current liabilities</b>	<b>271.8</b>	<b>316.9</b>	<b>2,855</b>
<b>Total liabilities</b>	<b>658.3</b>	<b>744.4</b>	<b>6,706</b>
<b>Equity</b>			
<b>Equity attributable to owners of the Company</b>			
Share capital	81.7	81.7	736
Capital surplus	505.6	505.9	4,558
Treasury shares	(47.3)	(47.3)	(426)
Retained earnings	1,266.4	1,229.4	11,075
Other components of equity	(13.2)	(65.2)	(587)
<b>Total equity attributable to owners of the Company</b>	<b>1,793.3</b>	<b>1,704.5</b>	<b>15,356</b>
<b>Non-controlling interests</b>	<b>28.7</b>	<b>27.8</b>	<b>250</b>
<b>Total equity</b>	<b>1,822.0</b>	<b>1,732.3</b>	<b>15,606</b>
<b>Total liabilities and equity</b>	<b>¥ 2,480.3</b>	<b>¥ 2,476.6</b>	<b>\$ 22,312</b>

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## Consolidated Financial Statements

Otsuka Holdings and its Subsidiaries for the year ended December 31, 2018

## Consolidated Statement of Income

	Billions of Yen		Millions of U.S. Dollars*
	2017.12	2018.12	2018.12
<b>Revenue</b>	¥ 1,240.0	¥ 1,292.0	\$ 11,639
Cost of sales	(422.5)	(441.8)	(3,980)
<b>Gross profit</b>	817.5	850.2	7,659
Selling, general and administrative expenses	(558.7)	(564.4)	(5,084)
Research and development expenses	(175.6)	(216.1)	(1,947)
Share of profit of associates	19.3	16.5	149
Other income	6.1	24.5	221
Other expenses	(4.4)	(2.3)	(21)
<b>Operating profit</b>	104.2	108.3	976
Finance income	4.3	9.2	83
Finance costs	(5.1)	(8.0)	(72)
Other non-operating income (expenses)	0.3	0	0
<b>Profit before taxes</b>	103.7	109.5	986
Income tax expenses	10.7	(24.1)	(217)
<b>Profit for the year</b>	¥ 114.4	¥ 85.4	\$ 769
<b>Attributable to:</b>			
Owners of the Company	112.5	82.5	743
Non-controlling interests	1.9	2.9	26
<b>Earnings per share:</b>	Yen		U.S. Dollars*
Basic earnings per share	¥ 207.60	¥ 152.24	\$ 1.37
Diluted earnings per share	206.99	151.26	1.36

## Consolidated Statement of Comprehensive Income

	Billions of Yen		Millions of U.S. Dollars*
	2017.12	2018.12	2018.12
<b>Profit for the year</b>	¥ 114.4	¥ 85.4	\$ 769
<b>Other comprehensive income</b>			
<b>Components that will not be reclassified to profit or loss</b>			
Remeasurements of defined benefit plans	1.9	(2.5)	(23)
Financial assets measured at fair value through other comprehensive income	17.0	(11.6)	(104)
Share of other comprehensive income of associates	0.5	(0.7)	(6)
Subtotal	19.5	(14.8)	(133)
<b>Components that may be reclassified to profit or loss</b>			
Foreign currency translation reserve	(4.5)	(26.3)	(237)
Cash flow hedges	(0)	0	0
Share of other comprehensive income of associates	8.4	(7.5)	(67)
Subtotal	4.0	(33.8)	(304)
<b>Total other comprehensive income</b>	23.4	(48.5)	(437)
<b>Comprehensive income</b>	¥ 137.8	¥ 36.9	\$ 332
<b>Attributable to:</b>			
Owners of the Company	135.3	35.4	319
Non-controlling interests	2.6	1.5	14

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## Consolidated Statement of Changes in Equity

	Billions of Yen										Non-controlling interests	Total equity
	Equity attributable to owners of the Company											
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Financial assets measured at fair value through other comprehensive income	Foreign currency translation reserve	Cash flow hedges	Total	Total		
<b>Balance as of January 1, 2017</b>	¥ 81.7	¥ 504.0	¥ (47.3)	¥ 1,209.1	—	¥ 22.4	¥ (59.4)	¥ 0.0	¥ (37.0)	¥ 1,710.5	¥ 27.9	¥ 1,738.4
Profit for the year	—	—	—	112.5	—	—	—	—	—	112.5	1.9	114.4
Other comprehensive income	—	—	—	—	2.1	17.4	3.3	(0.0)	22.8	22.8	0.7	23.4
<b>Comprehensive income</b>	—	—	—	112.5	2.1	17.4	3.3	(0.0)	22.8	135.3	2.6	137.8
Purchase of treasury shares	—	—	(0)	—	—	—	—	—	—	(0)	—	(0)
Dividends	—	—	—	(54.2)	—	—	—	—	—	(54.2)	(0.6)	(54.8)
Share-based payment transactions	—	0.2	—	—	—	—	—	—	—	0.2	—	0.2
Changes in ownership interests in subsidiaries that do not result in loss of control	—	1.4	—	—	—	—	0.0	—	0.0	1.4	(1.2)	0.3
Transfer from other components of equity to retained earnings	—	—	—	(1.0)	(2.1)	3.2	—	—	1.0	—	—	—
<b>Total transactions with owners, etc.</b>	—	1.6	0	(55.2)	(2.1)	3.2	0	—	1.1	(52.5)	(1.8)	(54.3)
<b>Balance as of December 31, 2017</b>	81.7	505.6	(47.3)	1,266.4	—	42.9	(56.1)	0.0	(13.2)	1,793.3	28.7	1,822.0
<b>Balance as of January 1, 2018</b>	¥ 81.7	¥ 505.6	¥ (47.3)	¥ 1,266.4	—	¥ 42.9	¥ (56.1)	¥ 0.0	¥ (13.2)	¥ 1,793.3	¥ 28.7	¥ 1,822.0
Changes in accounting policies	—	—	—	(70.2)	—	—	—	—	—	(70.2)	—	(70.2)
Restated balance	81.7	505.6	(47.3)	1,196.2	—	42.9	(56.1)	0.0	(13.2)	1,723.0	28.7	1,751.7
Profit for the year	—	—	—	82.5	—	—	—	—	—	82.5	2.9	85.4
Other comprehensive income	—	—	—	—	(2.7)	(12.0)	(32.5)	0.0	(47.1)	(47.1)	(1.4)	(48.5)
<b>Comprehensive income</b>	—	—	—	82.5	(2.7)	(12.0)	(32.5)	0.0	(47.1)	35.4	1.5	36.9
Purchase of treasury shares	—	—	(0.0)	—	—	—	—	—	—	0.0	—	0.0
Dividends	—	—	—	(54.2)	—	—	—	—	—	(54.2)	(1.1)	(55.3)
Share-based payment transactions	—	(0.0)	—	—	—	—	—	—	—	0.0	—	0.0
Changes in ownership interests in subsidiaries that do not result in loss of control	—	0.3	—	—	—	—	0.0	—	0.0	0.3	(0.8)	(0.5)
Disposal of subsidiaries	—	—	—	—	—	—	—	—	—	—	(0.5)	(0.5)
Transfer from other components of equity to retained earnings	—	—	—	4.9	2.7	(7.6)	—	—	(4.9)	—	—	—
<b>Total transactions with owners, etc.</b>	—	0.3	(0.0)	(49.3)	2.7	(7.6)	0	—	(4.9)	(53.9)	(2.4)	(56.3)
<b>Balance as of December 31, 2018</b>	¥ 81.7	¥ 505.9	¥ (47.3)	¥ 1,229.4	—	¥ 23.3	¥ (88.5)	¥ 0.0	¥ (65.2)	¥ 1,704.5	¥ 27.8	¥ 1,732.3

	Millions of U.S. Dollars*										Non-controlling interests	Total equity
	Equity attributable to owners of the Company											
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Financial assets measured at fair value through other comprehensive income	Foreign currency translation reserve	Cash flow hedges	Total	Total		
<b>Balance as of January 1, 2018</b>	\$ 736	\$ 4,555	\$ (426)	\$ 11,409	\$ —	\$ 387	\$ (505)	\$ (0)	\$ (119)	\$ 16,156	\$ 258	\$ 16,414
Changes in accounting policies	—	—	—	(633)	—	—	—	—	—	(633)	—	(633)
Restated balance	736	4,555	(426)	10,776	—	387	(505)	(0)	(119)	15,523	258	15,781
Profit for the year	—	—	—	743	—	—	—	—	—	743	26	769
Other comprehensive income	—	—	—	—	(25)	(108)	(292)	0	(425)	(425)	(13)	(437)
<b>Comprehensive income</b>	—	—	—	743	(25)	(108)	(292)	0	(425)	319	14	332
Purchase of treasury shares	—	—	(0)	—	—	—	—	—	—	(0)	—	(0)
Dividends	—	—	—	(488)	—	—	—	—	—	(488)	(10)	(498)
Share-based payment transactions	—	(0)	—	—	—	—	—	—	—	(0)	—	(0)
Changes in ownership interests in subsidiaries that do not result in loss of control	—	3	—	—	—	—	0	—	0	3	(7)	(4)
Disposal of subsidiaries	—	—	—	—	—	—	—	—	—	—	(5)	(5)
Transfer from other components of equity to retained earnings	—	—	—	44	25	(69)	—	—	(44)	—	—	—
<b>Total transactions with owners, etc.</b>	—	2	(0)	(444)	25	(69)	0	—	(44)	(486)	(22)	(507)
<b>Balance as of December 31, 2018</b>	\$ 736	\$ 4,558	\$ (426)	\$ 11,075	\$ —	\$ 210	\$ (797)	\$ 0	\$ (587)	\$ 15,356	\$ 250	\$ 15,606

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## Consolidated Statement of Cash Flows

	Billions of Yen		Millions of U.S. Dollars*
	2017.12	2018.12	2018.12
<b>Cash flows from operating activities</b>			
Profit before taxes	¥ 103.7	¥ 109.5	\$ 986
Depreciation and amortization expenses	62.2	59.3	534
Impairment loss and reversal of impairment loss	28.8	34.7	313
Share of loss (profit) of associates	(19.3)	(16.5)	(149)
Finance income	(4.3)	(9.2)	(83)
Finance costs	5.1	8.0	72
Other non-operating (income) expenses	(0.3)	—	—
Decrease (increase) in inventories	(8.4)	(17.4)	(157)
Decrease (increase) in trade and other receivables	(9.9)	(20.5)	(184)
Increase (decrease) in trade and other payables	(5.8)	16.3	147
Other	(12.3)	(6.5)	(59)
Subtotal	139.5	157.7	1,421
Interest and dividends received	10.2	10.6	96
Interest paid	(3.6)	(3.0)	(27)
Income taxes paid	(43.2)	(29.6)	(267)
<b>Net cash flows from (used in) operating activities</b>	<b>102.8</b>	<b>135.8</b>	<b>1,224</b>
<b>Cash flows from investing activities</b>			
Proceeds from sales of property, plant and equipment	0.5	0.5	4
Payments for acquisition of property, plant and equipment	(54.2)	(57.1)	(514)
Payments for acquisition of intangible assets	(23.4)	(16.5)	(149)
Proceeds from sales and redemption of investments	74.4	33.8	305
Payments for acquisition of investments	(48.4)	(32.1)	(290)
Payments for acquisition of subsidiaries	(47.1)	(68.1)	(614)
Decrease (increase) in time deposits	59.7	47.3	426
Other	(1.6)	(1.1)	(10)
<b>Net cash flows from (used in) investing activities</b>	<b>(40.1)</b>	<b>(93.3)</b>	<b>(841)</b>
<b>Cash flows from financing activities</b>			
Purchase of treasury shares	(0.0)	(0.0)	(0)
Increase (decrease) in current borrowings	(18.0)	4.0	36
Proceeds from non-current borrowings	25.5	6.5	59
Repayments of non-current borrowings	(40.0)	(41.8)	(376)
Dividends paid	(54.9)	(55.3)	(498)
Other	(7.2)	(2.7)	(24)
<b>Net cash flows from (used in) financing activities</b>	<b>(94.5)</b>	<b>(89.2)</b>	<b>(804)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(31.8)</b>	<b>(46.7)</b>	<b>(421)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>369.9</b>	<b>336.6</b>	<b>3,033</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(1.5)</b>	<b>(4.9)</b>	<b>(44)</b>
<b>Cash and cash equivalents at end of period</b>	<b>¥ 336.6</b>	<b>¥ 285.0</b>	<b>\$ 2,568</b>

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## Group Structure &amp; Overview of Main Operating Companies

## Otsuka Group Corporate Philosophy

Otsuka-people creating new products for better health worldwide



## Overview

The Otsuka group of companies, whose origins date back to 1921, aims to contribute to the health of people around the world. It aims to do so through two main pillars: the pharmaceutical business for the diagnosis and treatment of diseases and the nutraceutical\*1 business to support the maintenance and promotion of everyday health.

The company's culture, summarized in a few words as, "Ryukan-godo" (by sweat we recognize the way), "Jissho" (actualization) and "Sozosei" (creativity), have been fostered by successive Otsuka leaders. These are emphasized by our 47,000\*2 employees across 189 group companies in 30 countries and regions who strive to create and market unique products and services.

\*1. Nutraceuticals: nutrition + pharmaceuticals \*2. As of end of December, 2018

## Organizational Structure



## Otsuka Pharmaceutical Co., Ltd.

A holistic healthcare company supporting whole-body health, from helping to cure disease through to the promotion of everyday health

In keeping with its corporate philosophy, the company is expanding its operations along two core businesses: the pharmaceutical business, which provides breakthrough treatments for patients around the world, and the nutraceutical business, which helps healthy people become even healthier.

## Otsuka Pharmaceutical Factory, Inc.

Original company of the Otsuka group and a leader in IV solution with more than 70 years of experience in the intravenous solutions business in Japan

Based on its "The Best Partner in Clinical Nutrition" management vision, the company creates innovative products to meet a variety of needs: pharmaceuticals and medical devices, oral rehydration solutions and other medical foods, OTC drugs, and more. The company is expanding its businesses globally, mainly in Japan and Asia.

## Taiho Pharmaceutical Co., Ltd.

A pioneer of oral anticancer agents in Japan for half a century

"We strive to improve human health and contribute to a society enriched by smiles"—that is the corporate philosophy of Taiho Pharmaceuticals, an R&D-driven specialty pharmaceutical company specializing in the three fields of oncology, immunology & allergology, and urology. Particularly in the field of oncology, Taiho is well known as one of the leading companies in Japan and is also actively expanding its global presence. In the consumer healthcare business too it is focused on creating products that help people lead a life brimming with love based on its customer-first policy.

## Otsuka Warehouse Co., Ltd.

Contributing to people's health worldwide in the field of logistics

Since its founding, Otsuka Warehouse has been consistently engaging in logistics for pharmaceuticals and food products. It has built a common distribution platform for the Otsuka group in the three product areas of pharmaceuticals, food & beverages, and daily necessities. In recent years, the company has grown to offer logistics services outside the group.

## Otsuka Chemical Co., Ltd.

Creatively giving shape to the power of materials for customers and the future

With materials at the core of its operations, Otsuka Chemical aims to create products that bring prosperous living to society through ceaseless technological innovation. Its main business segments are the hydrazine business, inorganic & composite materials business, and pharmaceutical intermediate & active pharmaceutical ingredient (API) business. The company provides products to global markets in the areas of automotive, electrical & electronic equipment, housing, and healthcare.

## Otsuka Foods Co., Ltd.

Creating high value-added products that offer new dietary lifestyles since its founding in 1955

Taking "the company begins with people and food begins with spirit" as its motto, Otsuka Foods conducts businesses in the areas of foods and beverages, with "deliciousness, safety, peace of mind, and better health" as the spirit of foods among all employees. It will continue to develop as a company which delivers products that allow customers to live healthy lives and create new dreams through foods.

## Otsuka Medical Devices Co., Ltd.

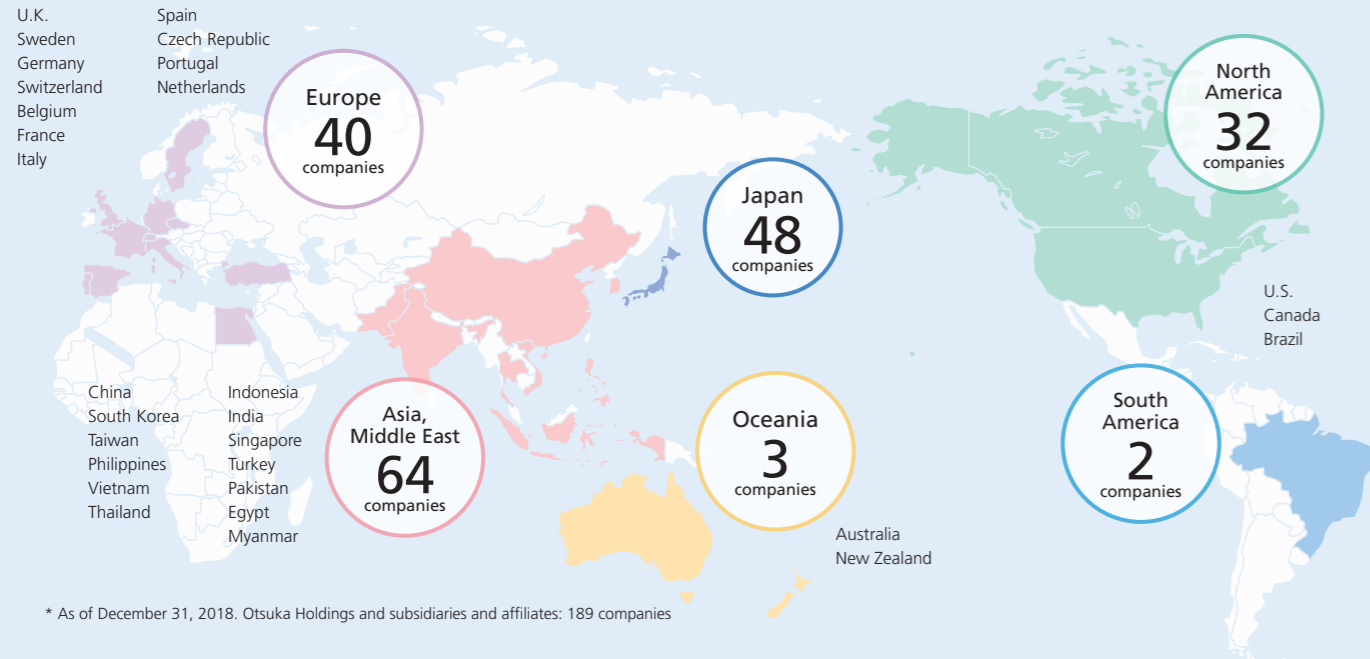
Aiming to make Otsuka's medical devices business unique by introducing new technologies

Otsuka Medical Devices seeks to grow its medical devices business, which operates mainly in Japan, China, and other Asian countries, into one of the group's core businesses in the future. The company is striving to spur further growth by bringing together the group's medical device experience and know-how, integrating new technology introductions into new devices, and thereby meeting new healthcare needs.

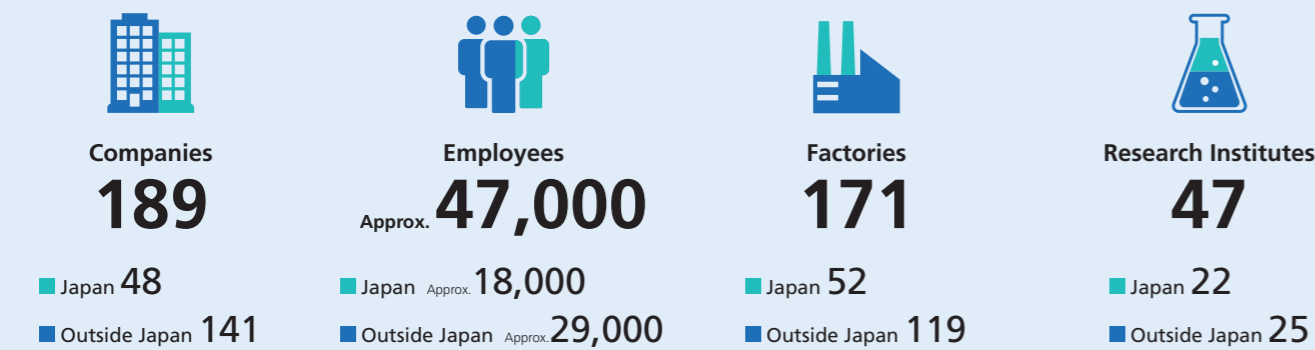
# Global Network

Otsuka operates in

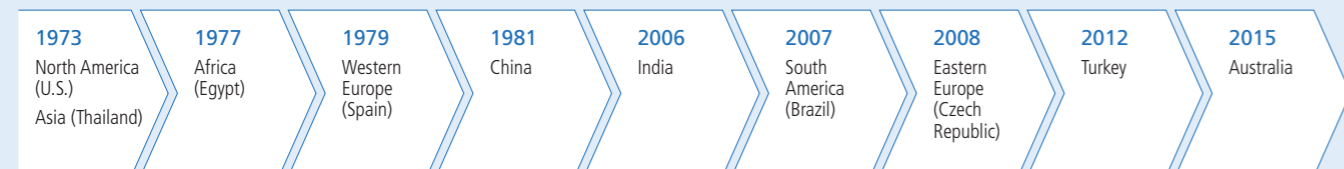
# 30 Countries and regions



## Number of operations and employees



## History of global business expansion



# Corporate Information/Shareholder Information

## Corporate Profile

(as of December 31, 2018)

<b>Company Name</b>	Otsuka Holdings Co., Ltd.
<b>Established</b>	July 8, 2008
<b>Capital</b>	¥ 81.69 billion
<b>Head Office</b>	2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan
<b>Tokyo Headquarters</b>	Shinagawa Grand Central Tower, 2-16-4 Konan, Minato-ku, Tokyo 108-8241, Japan
<b>Telephone</b>	+81-3-6717-1410
<b>Number of Employees</b>	94 (consolidated: 32,935)
<b>Business</b>	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.

## Shares

(as of December 31, 2018)

<b>Number of shares authorized</b>	1,600,000,000 shares
<b>Number of shares issued</b>	557,835,617 shares
<b>Number of shareholders</b>	54,112

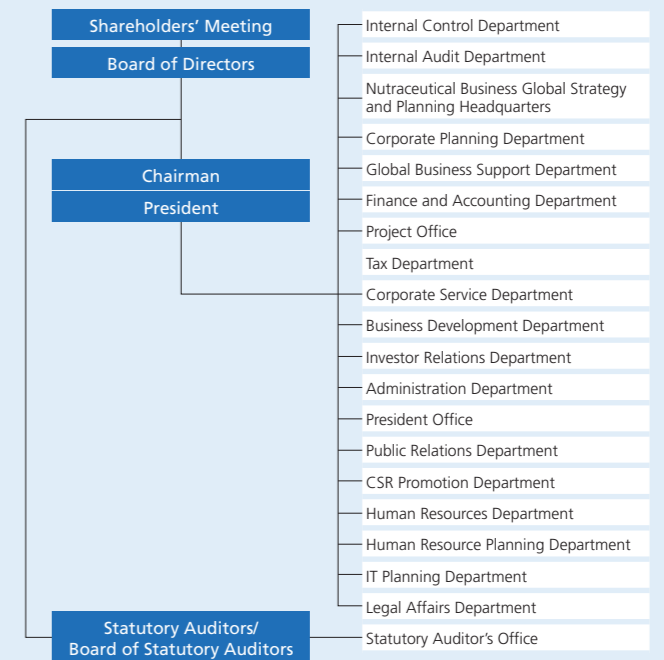
### Principal shareholders (top 10 shareholders)

Name of shareholder	Number of shares held (thousand)	Shareholding ratio (%)
The Nomura Trust and Banking Co., Ltd.	57,798	10.66
Otsuka Founders Shareholding Fund Trust Account		
The Master Trust Bank of Japan, Ltd. (trust account)	42,358	7.81
Japan Trustee Services Bank, Ltd. (trust account)	26,882	4.96
Otsuka Estate Co., Ltd.	23,296	4.29
Otsuka Group Employee Shareholding Fund	13,202	2.43
The Awa Bank, Ltd.	10,970	2.02
Japan Trustee Services Bank, Ltd. (trust account 9)	7,799	1.43
STATE STREET BANK WEST CLIENT - TREATY 505234	7,740	1.42
Japan Trustee Services Bank, Ltd. (trust account 5)	7,476	1.37
Otsuka Asset Co., Ltd.	7,380	1.36

- Number of shares held is rounded down to the nearest thousand.
- Although the Company holds 15,987,217 of its own shares, treasury shares are excluded from the above list.
- Shareholding ratio is calculated after treasury shares are deducted.

## Company organization

(as of April 1, 2019)



### Website information

Visit our website at:



Otsuka Holdings Website

<https://www.otsuka.com/en/>





# Otsuka

## Otsuka Holdings Co., Ltd.



### 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.



This is our **Communication on Progress** in implementing the principles of the **United Nations Global Compact** and supporting broader UN goals.

We welcome feedback on its contents.