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.
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.

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

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.
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.
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 healthcare 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

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.
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.

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.

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

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, SamsecaINARCI/JYNARQUE and LONGSURF, 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 Pharmaceuticals’s AVP-786, in development for several mental health disorders; and vandadutat, 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-mid-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.
Message from the President

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).

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
DELTBYA, 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.
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 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

Under the Plan, we categorized the antipsychotic agent (long-acting injectable) ABILIFY MAINTENA, antipsychotic agent REXULTI, and V2-receptor antagonist 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

<table>
<thead>
<tr>
<th>Year 2013</th>
<th>Year 2014</th>
<th>Year 2015</th>
<th>Year 2016</th>
<th>Year 2017</th>
<th>Year 2018</th>
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<tr>
<td>3 Global Products</td>
<td>New-generation products</td>
<td>New drugs in Japan</td>
<td>428.1bn</td>
<td>99.6%</td>
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Message from the President

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.

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 OROWAMY C DRINK, and entered into the plant-based business through the acquisition of Daya 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.

Accelerating Global Expansion

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<tr>
<th>Region</th>
<th>Asia</th>
<th>North America</th>
<th>Europe</th>
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<tbody>
<tr>
<td>Products</td>
<td>POCARI SWEAT</td>
<td>Plant-based food</td>
<td>Nutrition &amp; Sante’</td>
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<td></td>
<td>Established subsidiaries in Thailand and Philippines to strengthen sales</td>
<td>Entered the plant-based food sector by acquiring Daya Foods</td>
<td>Strengthened production system for ‘free-from’ products</td>
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<tr>
<td>Products</td>
<td>OROWAMY C DRINK</td>
<td>Nutritional supplements</td>
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<td></td>
<td>Established local production and sales in Indonesia</td>
<td>Magnetically</td>
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<tr>
<td>Products</td>
<td>KOSYODY</td>
<td>Started local production in Indonesia</td>
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* Due to a change in the consolidated fiscal year, fiscal 2018 ended on December 31, 2018. A transitional period covering the nine months from April 1 to December 31, 2018.

* Due to a change in the consolidated fiscal year, fiscal 2018 ended on December 31, 2018.
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 “Ryukian-godo” (Commitment), “Jisho” (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 business of pharmaceutical and nutraceuticals, we are going to maximize values of existing businesses and create new values while practicing the business management with a corporatewide 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 profit before R&D expenses will reach 460 billion yen, both of which are our record highs. Our target business profit for fiscal 2023 is ¥1,700 billion (the final year of the plan), among which R&D expenses will reach ¥460 billion, both of which will exceed our previous record. 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.

[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, Sansacal/NARCYN/MARGAREE, and LONSURF), three major brands (POCARI SWEAT, Nature Made, and Nutrition & Santé), and three nurture brands in NC business (Dayya Foods, QUELLE, and BODYMANIÉ). Additionally, Otsuka will launch and nurture new product lines that will drive sustainable growth in the pharmaceutical and NC businesses.

[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. 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.

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

Feature: Access to Medicine

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 death among infected individuals. 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 medical 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.

Feature: Access to Medicine

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.

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* WHO Global Tuberculosis Report 2018

Global Distribution of Tuberculosis Patients

- Global Distribution of Tuberculosis Patients
- Reference: WHO Global Tuberculosis Report 2018

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**DETYBA is improving global health**

One of the first new drugs in 50 years

**Birth of DETYBA**

"If nobody does it, Otsuka must do it."

DETYBA 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, DETYBA was included in the WHO Model List of Essential Medicines (list of priority drugs in any country).

DETYBA 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.” DETYBA 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.

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### DETYBA 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 of its key themes
- **1982** Full-scale research into tuberculosis drugs was started
- **2004** Clinical trials were started for OPC-67683 (later DETYBA) for the treatment of tuberculosis
- **2014** DETYBA was approved and launched in Europe and Japan as a therapeutic drug for multidrug-resistant tuberculosis (MDR-TB)
- **2015** DETYBA 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 DETYBA in Russia and 12 surrounding countries
- **2017** Licensing agreement was executed with Mylan of India to expand DETYBA approval and commercialization activities in high-burden countries

### Top Ten Funders of TB Research in 2017

<table>
<thead>
<tr>
<th>Funding Organization</th>
<th>Sector</th>
<th>Total Funding</th>
<th>Percent of Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. NIH</td>
<td>Public</td>
<td>245,461,895</td>
<td>32%</td>
</tr>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>Philanthropic</td>
<td>127,933,459</td>
<td>17%</td>
</tr>
<tr>
<td>USAID</td>
<td>Public</td>
<td>33,989,472</td>
<td>4%</td>
</tr>
<tr>
<td>Unitaid</td>
<td>Multilateral</td>
<td>28,566,016</td>
<td>4%</td>
</tr>
<tr>
<td>Otsuka Pharmaceuticals</td>
<td>Private</td>
<td>22,772,887</td>
<td>3%</td>
</tr>
<tr>
<td>U.K. DFID</td>
<td>Public</td>
<td>20,642,544</td>
<td>3%</td>
</tr>
<tr>
<td>Company R</td>
<td>Private</td>
<td>20,570,920</td>
<td>3%</td>
</tr>
<tr>
<td>European Commission</td>
<td>Public</td>
<td>19,275,723</td>
<td>3%</td>
</tr>
<tr>
<td>U.S. CDC</td>
<td>Public</td>
<td>18,216,200</td>
<td>2%</td>
</tr>
<tr>
<td>ECDC</td>
<td>Public</td>
<td>17,708,217</td>
<td>2%</td>
</tr>
</tbody>
</table>

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

DETYBA 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 DETYBA 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 delivery services to the public sector with a particular focus on providing technical assistance to TB programs and supporting wide-use of innovative tools.

---

**External Collaborations**

**DETYBA: Supply route via StopTB/GDF**

**Otsuka Novel Products GmbH**

**Medical institution/patient**

**GDF’s supply agency**

**Topics**

**Cooperation with Japanese government on DETYBA**

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

As a limited 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.

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.

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.

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

Interview

Establishing a supply network which will save patients around the world

Value Creation Section

26 Growth Trajectory
28 Seeking to provide value through business
30 Value Creation Model
32 Financial Highlights
34 Non-Financial Highlights
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 aqueduc therapeutic.

### Foundation phase

**Inception and growth**

- Started business in Naruto, Tokushima Prefecture in Japan
- 1921

**Production and expansion**

- Developed chemical raw material production
- 1946

**Quality and innovation**

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

### Growth phase

**Numerous innovative products**

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

**Pharmaceutical expansion**

- Started in-house pharmaceutical research and established the group’s business foundation to deliver total healthcare solutions via the twin business segments of pharmaceuticals and nutraceuticals
- 1971

**Leadership and vision**

- Otsuka became the first Japanese pharmaceutical company to establish a joint venture in China
- 1982

### Expansion phase

**International business development phase**

- Drawing on the advanced technological know-how cultivated in Japan, we started to expand the IV solutions business to overseas markets in the 1970s
- 1970s

**Global expansion and diversification**

- Drawing on the advanced technological know-how cultivated in Japan, we started to expand the IV solutions business to overseas markets in the 1970s

**Quality and innovation**

- “Quality is vital in a factory and so is packaging. We have to manufacture and market, putting ourselves in the consumer’s position.”

**International business development phase**

- Started aggressive global expansion

**Sustained growth and diversified operations**

- Seeking further global growth as a total healthcare company

**Quality and innovation**

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- Seeking further global growth as a total healthcare company
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.
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.

**Value Creation Model**

- **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

**Diverse business activities**

**Innovative products**

**Creation of social value**

---

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

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ billion</th>
<th>Overseas sales ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>1,292</td>
<td>50.0</td>
</tr>
<tr>
<td>2015</td>
<td>1,390</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>1,292</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>1,390</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>1,390</td>
<td></td>
</tr>
</tbody>
</table>

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.

### Operating profit

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ billion</th>
<th>Operating profit margin (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>108.3</td>
<td>8.4</td>
</tr>
<tr>
<td>2015</td>
<td>150.0</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>108.3</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>150.0</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>108.3</td>
<td></td>
</tr>
</tbody>
</table>

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.

### Profit attributable to owners of the Company

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ billion</th>
<th>Ratio of profit attributable to owners of the Company (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>82.5</td>
<td>26.7</td>
</tr>
<tr>
<td>2015</td>
<td>64.4</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>110.0</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>82.5</td>
<td></td>
</tr>
</tbody>
</table>

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.

### R&D expenses in pharmaceutical business

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ billion</th>
<th>R&amp;D expenses ratio in pharmaceutical business (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>205.7</td>
<td>24.3</td>
</tr>
<tr>
<td>2015</td>
<td>25.2</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>24.1</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>25.2</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>20.0</td>
<td></td>
</tr>
</tbody>
</table>

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.

### Total assets

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ billion</th>
<th>Ratio of equity attributable to owners of the Company to total assets (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>2,476.6</td>
<td>68.8</td>
</tr>
<tr>
<td>2015</td>
<td>2,476.6</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>2,476.6</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>2,476.6</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>2,476.6</td>
<td></td>
</tr>
</tbody>
</table>

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.

### Dividend per share

<table>
<thead>
<tr>
<th>Year</th>
<th>¥ per share</th>
<th>Dividend pay-out ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014*</td>
<td>100</td>
<td>65.7</td>
</tr>
<tr>
<td>2015</td>
<td>65.7</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>49.3</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>40.0</td>
<td></td>
</tr>
</tbody>
</table>

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

### Number of employees

<table>
<thead>
<tr>
<th>Year</th>
<th>(number)</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>32,935</td>
<td>58.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outside Japan</td>
<td>0</td>
<td>41.8%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

### Female manager ratio

<table>
<thead>
<tr>
<th>Year</th>
<th>(number)</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female manager ratio</td>
<td>8.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 employees acquiring childcare leave

<table>
<thead>
<tr>
<th>Year</th>
<th>(number)</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>287</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

### Total CO₂ emissions

<table>
<thead>
<tr>
<th>Year</th>
<th>(thousand tons-CO₂)</th>
<th>(ton/¥ million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>842</td>
<td>0.65</td>
</tr>
<tr>
<td>2017</td>
<td>842</td>
<td>0.70</td>
</tr>
<tr>
<td>2018</td>
<td>842</td>
<td>0.70</td>
</tr>
</tbody>
</table>

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.

### Energy composition (calorie conversion)

<table>
<thead>
<tr>
<th>Year</th>
<th>(number)</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>842</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>842</td>
<td>842</td>
<td>842</td>
<td>842</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>(thousand tons-CO₂)</th>
<th>GHG emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope 1</td>
<td>0.7%</td>
<td>1,399</td>
</tr>
<tr>
<td>Scope 2</td>
<td>12.8%</td>
<td>1,399</td>
</tr>
<tr>
<td>Scope 3</td>
<td>80.2%</td>
<td>1,399</td>
</tr>
</tbody>
</table>

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.

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*Scope: Otsuka Holdings and its 162 subsidiaries

*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.

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Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

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Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

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Value Creation Section
Non-Financial Highlights

## Water usage and water use efficiency

<table>
<thead>
<tr>
<th>Year</th>
<th>Water Usage (thousand m³)</th>
<th>Resource Recycling Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>19,463</td>
<td>99.5</td>
</tr>
<tr>
<td>2017</td>
<td>16,452</td>
<td>98.0</td>
</tr>
<tr>
<td>2018</td>
<td>13,010</td>
<td>97.0</td>
</tr>
</tbody>
</table>

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.

### Resource recycling rate and final disposal amount

<table>
<thead>
<tr>
<th>Final Disposal Amount</th>
<th>Resource Recycling Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>166</td>
</tr>
<tr>
<td>2017</td>
<td>96.0</td>
</tr>
<tr>
<td>2018</td>
<td>95.0</td>
</tr>
</tbody>
</table>

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).

### 2030 Target:

- Improve water use efficiency by 15% compared to 2017

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Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

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Business Strategy Section

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38 R&D Activities

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50 Nutraceutical Business

50 Social Challenges/Strengths/Overview

52 Global Expansion

54 R&D Framework

55 Consumer Products Business

56 Other Businesses

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10th 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.

R&D Activities—Pharmaceutical Business

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 intraintravenous solutions. We have also welcomed into the group Actex 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.

R&D bases

Basic research
Clinical development

Topics

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 targeting hitherto considered difficult. We thus aim to provide new therapeutic drugs for diseases where unmet medical needs still remain.
Cerebral edema
OPC-61815

PIII-US/Europe, Dec 2020
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 independent processes, 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. 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

[ brexiprazole ]
Brexiprazole 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 REVLAX 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 use the properties of this agent in order to provide effective methods of treatment in other unmet fields, such as agitation associated with dementia of the Alzheimer’s type or post-traumatic stress disorder (PTSD).

It is estimated that approximately 10 million 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 not just on 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, 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 is estimated to be around 20 million*2. 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.

[ 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.

[ avp-786 ]
AVP-786 is a new compound of deuterium-modified dextroamphetamine 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*3. 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.

[ guadecitabine ]
Guadecitabine is a next-generation, low-molecular-weight DNA methyltransferase inhibitor that is designed to allow the active metabolite deacitabine 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.

[ astx727 ]
ASTX727 is the world’s first oral DNA methyltransferase inhibitor combination drug containing the DNA methyltransferase inhibitor deacitabine 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 II 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 in a highly activated state. A Phase I 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.

Business Strategy Section

Psychiatry & Neurology

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## Projects in Phase II and later stages (as of March 31, 2018)

### Psychiatry & Neurology

<table>
<thead>
<tr>
<th>Code (Generic name)</th>
<th>Origin</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC-34172 (Brexpiprazole)</td>
<td>Otsuka Pharmaceutical</td>
<td>Major depressive disorder</td>
<td>JP, EU, CN</td>
<td>Filed</td>
</tr>
<tr>
<td>TBI-1501</td>
<td>Teva Pharmaceutical</td>
<td>Ataxia of hereditary ataxia syndrome</td>
<td>US, EU</td>
<td>Filed</td>
</tr>
<tr>
<td>Pro-NETU (fosnetupitant)</td>
<td>Otsuka Pharmaceutical</td>
<td>Posttraumatic stress disorder</td>
<td>US, EU</td>
<td>Filed</td>
</tr>
</tbody>
</table>

### Oncology

<table>
<thead>
<tr>
<th>Code (Generic name)</th>
<th>Origin</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAS-102 (tifluridine, tipiracil)</td>
<td>Teva Pharmaceutical</td>
<td>Colorectal cancer</td>
<td>CN</td>
<td>Fielded</td>
</tr>
<tr>
<td>TBI-114</td>
<td>Teva Pharmaceutical</td>
<td>Gastric cancer</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>TBI-116</td>
<td>Teva Pharmaceutical</td>
<td>Prostate cancer</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>TBI-120</td>
<td>Teva Pharmaceutical</td>
<td>Breast cancer</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>TBI-35513</td>
<td>Teva Pharmaceutical</td>
<td>Urothelial cancer</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>TBI-35728</td>
<td>Teva Pharmaceutical</td>
<td>Solid tumors</td>
<td>US, EU</td>
<td>Filed</td>
</tr>
</tbody>
</table>

### Cardiovascular & Renal

<table>
<thead>
<tr>
<th>Code (Generic name)</th>
<th>Origin</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPC-41601 (ilivaptan)</td>
<td>Otsuka Pharmaceutical</td>
<td>Syndrome of inappropriate antidiuretic hormone secretion</td>
<td>US</td>
<td>Filed</td>
</tr>
<tr>
<td>OPC-6151</td>
<td>Otsuka Pharmaceutical</td>
<td>Cardiac edema</td>
<td>US</td>
<td>Filed</td>
</tr>
<tr>
<td>ALR-8118 (delisertib)</td>
<td>Alkios</td>
<td>Acute myeloid leukemia</td>
<td>US, EU</td>
<td>Filed</td>
</tr>
</tbody>
</table>

### Other areas

<table>
<thead>
<tr>
<th>Code (Generic name)</th>
<th>Origin</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AKB-6548 (vadadustat)</td>
<td>Akebia</td>
<td>Anemia associated with chronic kidney disease</td>
<td>US, EU</td>
<td>Fielded</td>
</tr>
<tr>
<td>OPC-167832</td>
<td>Otsuka Pharmaceutical</td>
<td>Tuberculosis</td>
<td>US</td>
<td>Fielded</td>
</tr>
<tr>
<td>DPA-1584</td>
<td>Otsuka Pharmaceutical</td>
<td>Atopic dermatitis</td>
<td>US</td>
<td>Fielded</td>
</tr>
<tr>
<td>TAS-393</td>
<td>Otsuka Pharmaceutical</td>
<td>Stress urinary incontinence</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>TAS-115</td>
<td>Otsuka Pharmaceutical</td>
<td>idiopathic pulmonary fibrosis</td>
<td>US</td>
<td>Filed</td>
</tr>
<tr>
<td>TASS315</td>
<td>Otsuka Pharmaceutical</td>
<td>Rheumatoid arthritis</td>
<td>JP</td>
<td>Filed</td>
</tr>
<tr>
<td>OPR-105</td>
<td>Otsuka Pharmaceutical</td>
<td>Peripheral neuronal nutrition solution</td>
<td>US</td>
<td>Filed</td>
</tr>
<tr>
<td>VIS410</td>
<td>Visterra</td>
<td>Influenza A infection</td>
<td>US</td>
<td>Fielded</td>
</tr>
<tr>
<td>TAC-302</td>
<td>Nippon</td>
<td>Distal ureteric obstruction with overactive bladder</td>
<td>JP</td>
<td>Fielded</td>
</tr>
</tbody>
</table>

### Diagnostics

<table>
<thead>
<tr>
<th>Code (Generic name)</th>
<th>Origin</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OOK-1003-CN</td>
<td>Otsuka Pharmaceutical</td>
<td>Diagnosis for Myeloproliferative syndromes</td>
<td>CN</td>
<td>Fielded</td>
</tr>
</tbody>
</table>

*3 Application by Takara Bio Inc.
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 standpoint 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

A corporate culture that generates innovation

Each and every Otsuka group employee has a high regard for jisho (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.

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.

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%).

ABILIFY MAINTENA

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 disorder in adults as an approved indication in the US.

REXULTI

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.

Samsca/JINARC/JYNARQUE

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 receptor antagonist. 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, tracing the use of Abilify Mycite, the world’s first digital medicine system for patients to record their tablet ingestions, 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.

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 Fautrafal 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, andoteracil 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 methyltransferase inhibitors guadecitabine and ASTX727, successor drugs it developed by leveraging its knowledge of Dacogen (generic name: desatinib), 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 engaged in open innovation initiatives, we seek to promote access to cutting-edge knowledge and innovative technology and achieve an even higher level of drug discovery.

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 725,000 people die of gastric cancer every year.* 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.**

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.


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 flaring, 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 log-term therapy and support aimed at return to society, while ameliorating symptoms. Another issue is 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.

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 MitoKalen, launched in 1980, we have continued to contribute to the treatment of cardiovascular diseases thanks to our ground-breaking novel drug discovery. Notably, the antplatelet agent Pletal and the world’s first oral aquatics 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 valadustat business alliance with Akebia Therapeutics and the acquisition of Vertexa, a company with a product pipeline in the renal domain.

We also strive to find solutions to unmet needs in non-pharmacological 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.

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.

Otsuka group’s market share of Intravenous solutions in Japan (2018)

55.8%

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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 abdomen distention 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 2,080–8,000 people and there are estimated to be roughly 30,000 patients in Japan and about 140,000 in the US.

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 aquatics 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 diagnostic indicators had to be established. Each condition was cleared in clinical trials conducted on more than 1,400 patients in 15 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 drug has been highly praised by the medical professionals alike and in May 2018 Otsuka was selected to receive the Corporate Innovation Award from the US National Kidney Foundation.

Taking an aquatics 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 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 project 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 hope 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

Robert McQuade (seated), Chief Executive Officer (CEO) of Otsuka Pharmaceutical Development & Commercialization receiving an award from the National Kidney Foundation.

Kevin Longino (pictured right), Chief Executive Officer of Nephrology & MDD Sales & Marketing, Otsuka America Pharmaceutical, Inc., receiving an award from the National Kidney Foundation.
Nutraceutical Business (NC Business)

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

Social Challenges/Strengths/Overview

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. Tivita Drink, an energy drink containing taurine, vitamins, and caffeine chloride, ORONAMIN C DRINK, a carbonated energy drink containing multiple vitamins, and the high-fiber drink Fibe-Mix, 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 Calore-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 equal to support women’s health and beauty. Kenya-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, DTC products like Onraine H Ointment for treating skin ailments and cuts, and our cosme

*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.

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, we expanded our reach by setting up production sites in 52 countries and regions 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 OROAMIN C DRINK and SOYJOY at our plant there and commenced production and sales of those products in Indonesia in 2018.

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.

PharmaViva, 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.


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 ISO, 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.

Innovative research has helped Otsuka advance beyond the treatment of traditional diseases and into the healthcare of conditions related to an expanding healthy life expectancy, such as healthy aging and longevity. We aim to maintain and improve people’s health through our innovative products based on scientific evidence that use our know-how in the pharmaceutical business to develop and provide the world with new solutions for the following global challenges:

- Expanding healthy life expectancy
- Women’s empowerment
- Cardiovascular diseases
- Women’s health
- Sports nutrition
- Populations in harsh environments

R&D Framework —Product development based on scientific evidence—

Otsuka’s R&D activities involve various research fields related to address exercise and nutrition, women’s health, and other health issues. In 2014, Otsuka established a new research institute for clinical exercise and nutrition 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.

The Otsuka 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.

Using science to support women’s vital and energetic lives

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 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 conducted by the Saga Nutraceuticals Research Institute discovered there to be a close relationship between women’s health and equol, an isoflavonoid estrogen metabolized from soy bean isoflavones by bacterial flora in the intestines. The institute successfully isolated lactobacillus 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 bacterium that produces equol. Using this lactic acid bacteria to produce equol by fermenting soy germ, we finally created the equol-containing supplement in 2014 after 18 years of research. 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.

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 knowledge 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 50th 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

Consumer Products Business

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

Business Strategy Section

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 knowledge 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.

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*Excluding the Ganso Bon Curry limited to sale in Okinawa

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, GEFSER 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.

Sales Revenue (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>2018.12</th>
<th>2017.12</th>
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<tbody>
<tr>
<td>Sales Revenue</td>
<td>6.7</td>
<td>11.1</td>
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<tr>
<td>Operating profit</td>
<td>3.6</td>
<td>3.3</td>
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</table>

Revenue from sales to external customers
Other Businesses

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

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.

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%).
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

<table>
<thead>
<tr>
<th>Materiality</th>
<th>Social Issues</th>
<th>Our Goals</th>
<th>Our Activities</th>
<th>Related SDGs</th>
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<tr>
<td>Society</td>
<td>Health</td>
<td>• Unmet medical and health needs • Spread of infections diseases • Nutritional needs • Increasing aging issues</td>
<td>• Contribution to unmet needs solution • Evaluation of tuberculosis • Creation of a system for the realization of a healthful life • Healthy life extension</td>
<td>• Promotion of R&amp;D for unmet needs • R&amp;D of antibiotics/drugs and improvement of drug access • Support for people’s health maintenance / improvement mainly on exercise and nutrition etc., enlightenment activities</td>
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<tr>
<td>People</td>
<td>Health</td>
<td>• Presentism*1 • Unagreed to diversification</td>
<td>• Creation of a corporate culture that stimulates creativity • Enhance employee engagement</td>
<td>• Human resource development • Diversity promotion • Health management</td>
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<tr>
<td>Quality</td>
<td>Climate change</td>
<td>• Consumption and production that impairs sustainability</td>
<td>• Gaining stakeholder trust • Pursuing sustainability at all levels of the value chain • Establishing a quality assurance system for safety and security</td>
<td>• Sustainable procurement and product design • Thorough quality control and stable supply • Responsible promotional activities and information provision • Deepening communication with stakeholders • Promotion of “Customer-oriented management”</td>
</tr>
<tr>
<td>in all we do</td>
<td>Resource circulation</td>
<td>• Environmental load increase</td>
<td>• FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019*2</td>
<td>• Reduce environmental impact by improving resource efficiency • Promotion of business activities aimed at a sustainable state in both society and the earth</td>
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<tr>
<td>Quality</td>
<td>Water conserva-</td>
<td>• Reducing freshwater availability</td>
<td>• FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017</td>
<td>• Understanding water resources risk • Management and effective use of water resources</td>
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<td>in all we do</td>
<td>Governance</td>
<td>• Fragile governance system • Social change risk</td>
<td>• Long-term improvement of corporate value</td>
<td>• Strengthen corporate governance • Thorough compliance • Risk identification, evaluation and management</td>
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</table>

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 | Businesses should support and respect the protection of internationally proclaimed human rights, and, if they个多 | Environment | Principle 9 | Businesses should support a precautionary approach to environmental challenges, | |
|             | Principle 2 | make sure that they are not complicit in human rights abuses | | Principle 8 | undertake initiatives to promote greater environmental responsibility, | |
|             | Principle 3 | Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining | Labour | Principle 10 | encourage the development and diffusion of environmentally friendly technologies, | |
|             | Principle 4 | the elimination of all forms of forced and compulsory labour | | | | |
|             | Principle 5 | the elimination of child labour, and | | | | |
|             | Principle 6 | the elimination of discrimination in respect of employment and occupation | | | | |

| Foundation of Value Creation |

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<td>Society</td>
<td>Health</td>
<td>• Unmet medical and health needs • Spread of infections diseases • Nutritional needs • Increasing aging issues</td>
<td>• Contribution to unmet needs solution • Evaluation of tuberculosis • Creation of a system for the realization of a healthful life • Healthy life extension</td>
<td>• Promotion of R&amp;D for unmet needs • R&amp;D of antibiotics/drugs and improvement of drug access • Support for people’s health maintenance / improvement mainly on exercise and nutrition etc., enlightenment activities</td>
</tr>
<tr>
<td>People</td>
<td>Health</td>
<td>• Presentism*1 • Unagreed to diversification</td>
<td>• Creation of a corporate culture that stimulates creativity • Enhance employee engagement</td>
<td>• Human resource development • Diversity promotion • Health management</td>
</tr>
<tr>
<td>Quality</td>
<td>Climate change</td>
<td>• Consumption and production that impairs sustainability</td>
<td>• Gaining stakeholder trust • Pursuing sustainability at all levels of the value chain • Establishing a quality assurance system for safety and security</td>
<td>• Sustainable procurement and product design • Thorough quality control and stable supply • Responsible promotional activities and information provision • Deepening communication with stakeholders • Promotion of “Customer-oriented management”</td>
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<tr>
<td>in all we do</td>
<td>Resource circulation</td>
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<td>• FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019*2</td>
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<tr>
<td>Quality</td>
<td>Water conserva-</td>
<td>• Reducing freshwater availability</td>
<td>• FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017</td>
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<tr>
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<td>Governance</td>
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<td>• Long-term improvement of corporate value</td>
<td>• Strengthen corporate governance • Thorough compliance • Risk identification, evaluation and management</td>
</tr>
</tbody>
</table>

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 | Businesses should support and respect the protection of internationally proclaimed human rights, and, if they个多 | Environment | Principle 9 | Businesses should support a precautionary approach to environmental challenges, | |
|             | Principle 2 | make sure that they are not complicit in human rights abuses | | Principle 8 | undertake initiatives to promote greater environmental responsibility, | |
|             | Principle 3 | Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining | Labour | Principle 10 | encourage the development and diffusion of environmentally friendly technologies, | |
|             | Principle 4 | the elimination of all forms of forced and compulsory labour | | | | |
|             | Principle 5 | the elimination of child labour, and | | | | |
|             | Principle 6 | the elimination of discrimination in respect of employment and occupation | | | | |
The Otsuka group CSR: Society

Policy
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.

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 REFLIXL, an antipsychotic drug, and Selank, 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 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 REFLIXL, an antipsychotic drug, and Selank, 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.

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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.

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 Welcome 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 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.
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 hydration 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.

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-rearing, 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.

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 furthering 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 sustainable growth in the Middle and Longer-term, as well as significant growth in corporate value. In 2016 we launched Otsuka Global Academy, human resources 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 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.

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**1 and UN Women**2 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.

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

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

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 TO-K-I, 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.

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.

External Recognition

Platinum Kurumin & Kurumin (Ministry of Health, Labour and Welfare, Tokyo Stock Exchange)

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.

Platinum Kurumin is a certification for Kurumin certified companies that have carried out high-level initiatives.

Otsuka Chemical: Gise 3 (top rank)

Excellent Corporation for Health Management

Certified in 2019: Otsuka Holdings, Otsuka Pharmaceutical, Otsuka Electronics, JIMRO, Otsuka Wellness Vending

Procedures and quality control

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

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. For instance, Global Product Quality Meeting was held in 2017 at Otsuka Pharmaceutical and attended by around 100 people, including managers and quality supervisors, to discuss the characteristics of each of our business lines, namely, pharmaceuticals, foods, beverage, chemicals and, cosmetics. 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 audits on our 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.

Based on the corporate philosophy of “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 will fulfill our social responsibility for human rights, labor, environment and support for local communities.

4. Compliance
   While abiding by 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 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

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, 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.

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*Questions are sent to business partners that correspond to predefined criteria.

Otsuka Group Sourcing / Procurement Vision & Policy

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Sales

Basic Policy
We believe the Otsuka group is obligated to provide high-value products and services to our customers by engaging in appropriate and legally compliant business practices. We recognize the importance of ensuring that our activities are in accordance with the law and regulations, and we are committed to promoting a culture of ethical behavior among our employees.

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 GMP*1 and GVP*2.

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 this context, 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.

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.

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 launched 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 Meprin 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 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 Tovita 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
   1. Our daily business with constant attention 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 mindsets of employees so that we may stay ahead 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 customers 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 even better products and services.

October, 2018

*1 Good Quality Practice
*2 Good Vigilance Practice
*3 Pharmaceutical Vigilance

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 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 planned 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.

Resource Circulation

In aiming to achieve a sound 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%).

Climate Change

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 CO₂ 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 CO₂ 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 (Scope 1 and 2, and categories 1, 2 and 11 of Scope 3)*1 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.

Initiatives aimed at zero emissions

The Otsuka group company carry out material recycling* and thermal recycling*2 of generated waste as required. In fiscal 2018 our 14 group companies in Japan achieved zero emissions with a recycling rate of 99.9%. They have also reduced thermal 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 Scope 1: Direct emissions
*2 Scope 2: Indirect emissions from energy sources
*3 Scope 3: Other indirect emissions
*4 5 companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical factory, Tahto Pharmaceutical, Otsuka Chemical, and Otsuka Foods

Resource recycling rate and final disposal amount**

Water Conservation

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.

*3 14 major consolidated subsidiaries in Japan.

*4 The use of thermal energy generated from incineration of waste.

*5 14 major consolidated subsidiaries in Japan.

*6 5,000 thousand tons-CO₂
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 Company's performance of its duties in collaboration with the Internal Audit Department, as well as the Accounting Auditor. The Company articulates its basic approach to corporate governance in its Corporate Governance Guidelines.

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


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

<table>
<thead>
<tr>
<th>Form of organization</th>
<th>Company with an Audit &amp; Supervisory Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board of Directors</td>
<td>12</td>
</tr>
<tr>
<td>of which outside directors</td>
<td>3 (independent directors)</td>
</tr>
<tr>
<td>Term of directors</td>
<td>One year</td>
</tr>
<tr>
<td>Audit &amp; Supervisory Board members</td>
<td>4</td>
</tr>
<tr>
<td>of which outside Audit &amp; Supervisory Board members</td>
<td>3 (independent directors)</td>
</tr>
<tr>
<td>Accounting auditor</td>
<td>Deloitte Touche Tohmatsu LLC</td>
</tr>
</tbody>
</table>

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 Corporate Governance, 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 the 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 reviewing 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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Rationale for selection</th>
<th>No. of times attended (FY2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuko Matsunari</td>
<td>Mr. Matsunari has been giving effective advice to the Company’s managers from a neutral and expertise 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. Matsunari to be suitable as an independent director.</td>
<td>13/13 —</td>
</tr>
<tr>
<td>Ko Sekiguchi</td>
<td>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 expertise 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.</td>
<td>10/10 —</td>
</tr>
<tr>
<td>Yoshinobu Aoki*</td>
<td>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 insightful advice to the Company’s management from an objective and expertise 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.</td>
<td>— —</td>
</tr>
<tr>
<td>Hiroshi Sugawara</td>
<td>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 &amp; supervisory board member.</td>
<td>13/13 16/16</td>
</tr>
<tr>
<td>Yoko Wachi</td>
<td>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 &amp; supervisory board member.</td>
<td>13/13 16/16</td>
</tr>
<tr>
<td>Kazuo Takahashi</td>
<td>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 &amp; supervisory board member.</td>
<td>10/10 13/13</td>
</tr>
</tbody>
</table>

*The number of Board of Directors meeting and Audit & Supervisory Board meetings attended by outside director Yoshinobu Aoki is not listed because he was newly appointed at the 111th General Meeting of Shareholders held on March 26, 2019.

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 an 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.

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.

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 comprehensive remuneration system that reflects the attainment of Medium-Term Management Plan, combining multiple conditions of earnings achievement based on the earnings indicators in our 3rd Medium-Term Management Plan.  
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 2018 will also apply to roughly 40 directors (excluding outside directors) at some of the group’s major subsidiaries.

Independence Standards for Outside Directors (Corporate Governance Guidelines B. (3))

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

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 (such as “Executive”) of the Company or one 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 transactions is 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.
Compliance

Basic Policy

Legal compliance forms the cornerstone of all our business activities. The Otsuka group possesses high ethical standards and we aim to achieve sustained growth along with earning the trust of our customers by conducting our business activities honestly.

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. The Otsuka group has 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 regular meetings to share the progress of initiatives in each country, and 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 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 is in accordance with relevant laws and regulations in each country and region 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.

Approach

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

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.
Directors, Audit & Supervisory Board Members

(as of March 26, 2018)

President and Representative Director, CEO
Yoshiro Matsuo

Chairman and Representative Director
Ichiro Otsuka

Senior Managing Director

Executive Director

Executive Director

Executive Director

Executive Director

Directors, Audit & Supervisory Board Members

Standing Audit & Supervisory Board Member
Yoza Toba

Audit & Supervisory Board Member
Hiroshi Sugawara

Audit & Supervisory Board Member
Yoko Wachi

Audit & Supervisory Board Member
Kazuo Takahashi

From left: Noriko Tojo, Yoshio Aski, Sadanobu Tobe, Yoshiro Matsuo, Ko Seikiguchi, Ichiro Otsuka

Tetsuo Higuchi, Yozo Toba, Yoshiro Aski, Hiroshi Sugawara, Shuichi Takagi, Yoko Wachi, Atsumasa Makise, Kazuo Takahashi, Masayuki Kobayashi

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

Foundation of Value Creation

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018
Main Data

With effects 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.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Results of Operations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>¥ 1,127.6</td>
<td>¥ 1,154.6</td>
<td>¥ 1,218.1</td>
<td>¥ 1,452.8</td>
<td>¥ 1,224.3</td>
<td>¥ 1,427.4</td>
<td>¥ 1,195.5</td>
<td>¥ 1,240.0</td>
<td>¥ 1,292.0</td>
</tr>
<tr>
<td>Selling, general and administrative expenses*2</td>
<td>¥ 457.6</td>
<td>¥ 457.4</td>
<td>¥ 462.2</td>
<td>¥ 563.4</td>
<td>¥ 508.6</td>
<td>¥ 636.4</td>
<td>¥ 535.9</td>
<td>¥ 558.7</td>
<td>¥ 564.4</td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>¥ 167.4</td>
<td>¥ 159.2</td>
<td>¥ 192.4</td>
<td>¥ 249.0</td>
<td>¥ 172.9</td>
<td>¥ 202.7</td>
<td>¥ 168.8</td>
<td>¥ 175.6</td>
<td>¥ 216.1</td>
</tr>
<tr>
<td>R&amp;D ratio (%)</td>
<td>14.6%</td>
<td>13.8%</td>
<td>15.8%</td>
<td>17.1%</td>
<td>14.1%</td>
<td>14.2%</td>
<td>14.1%</td>
<td>14.2%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Operating profit</td>
<td>¥ 126.3</td>
<td>¥ 148.7</td>
<td>¥ 169.7</td>
<td>¥ 198.7</td>
<td>¥ 196.5</td>
<td>¥ 148.9</td>
<td>¥ 101.1</td>
<td>¥ 104.2</td>
<td>¥ 108.3</td>
</tr>
<tr>
<td>Operating profit margin (%)</td>
<td>11.2%</td>
<td>12.9%</td>
<td>13.9%</td>
<td>13.7%</td>
<td>16.7%</td>
<td>14.2%</td>
<td>8.5%</td>
<td>8.4%</td>
<td>8.4%</td>
</tr>
<tr>
<td>Net cash flows from operating activities</td>
<td>¥ 87.7</td>
<td>¥ 147.6</td>
<td>¥ 119.3</td>
<td>¥ 226.5</td>
<td>¥ 88.5</td>
<td>¥ 257.9</td>
<td>¥ 142.0</td>
<td>¥ 102.8</td>
<td>¥ 135.8</td>
</tr>
<tr>
<td>Net cash flows from investing activities</td>
<td>(131.5)</td>
<td>(107.6)</td>
<td>(91.2)</td>
<td>(108.5)</td>
<td>(28.7)</td>
<td>(422.6)</td>
<td>(135.1)</td>
<td>(40.1)</td>
<td>(841)</td>
</tr>
<tr>
<td>Free cash flows</td>
<td>(43.8)</td>
<td>40.0</td>
<td>28.1</td>
<td>117.9</td>
<td>59.9</td>
<td>164.7</td>
<td>6.9</td>
<td>62.8</td>
<td>42.5</td>
</tr>
<tr>
<td>Dividends</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual dividend per share (yen)</td>
<td>¥ 28</td>
<td>¥ 45</td>
<td>¥ 58</td>
<td>¥ 65</td>
<td>¥ 75</td>
<td>¥ 100</td>
<td>¥ 100</td>
<td>¥ 100</td>
<td>¥ 100</td>
</tr>
<tr>
<td>Dividend pay-out ratio (%)</td>
<td>17.3%</td>
<td>27.2%</td>
<td>26.1%</td>
<td>23.4%</td>
<td>28.4%</td>
<td>53.1%</td>
<td>58.5%</td>
<td>48.2%</td>
<td>65.7%</td>
</tr>
<tr>
<td>Common Stock/Stock Price</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Number of shares outstanding at year-end (thousand shares)</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
<td>557,836</td>
</tr>
<tr>
<td>Stock price at year-end (yen)</td>
<td>¥ 2,055</td>
<td>¥ 2,450</td>
<td>¥ 3,300</td>
<td>¥ 3,087</td>
<td>¥ 3,617</td>
<td>¥ 3,417</td>
<td>¥ 5,093</td>
<td>¥ 4,948</td>
<td>¥ 4,493</td>
</tr>
<tr>
<td>Number of Employees*4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (persons)</td>
<td>25,188</td>
<td>24,595</td>
<td>25,330</td>
<td>28,288</td>
<td>29,482</td>
<td>28,288</td>
<td>29,482</td>
<td>28,288</td>
<td>29,482</td>
</tr>
<tr>
<td>Outside Japan (persons)</td>
<td>11,158</td>
<td>10,787</td>
<td>11,598</td>
<td>14,792</td>
<td>15,197</td>
<td>17,858</td>
<td>17,878</td>
<td>18,937</td>
<td>19,178</td>
</tr>
<tr>
<td>Female Manager Ratio*6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of female managers (persons)</td>
<td>187</td>
<td>202</td>
<td>226</td>
<td>248</td>
<td>269</td>
<td>270</td>
<td>280</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female manager ratio (%)</td>
<td>4.8%</td>
<td>5.3%</td>
<td>6.1%</td>
<td>7.0%</td>
<td>7.7%</td>
<td>7.8%</td>
<td>8.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental Data*7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total CO2 emissions (thousand tons-CO2)</td>
<td>801</td>
<td>818</td>
<td>842</td>
<td>801</td>
<td>818</td>
<td>842</td>
<td>801</td>
<td>818</td>
<td>842</td>
</tr>
<tr>
<td>Japan (%)</td>
<td>42.8%</td>
<td>39.8%</td>
<td>38.5%</td>
<td>42.8%</td>
<td>39.8%</td>
<td>38.5%</td>
<td>42.8%</td>
<td>39.8%</td>
<td>38.5%</td>
</tr>
<tr>
<td>Outside Japan (%)</td>
<td>57.2%</td>
<td>60.2%</td>
<td>61.5%</td>
<td>57.2%</td>
<td>60.2%</td>
<td>61.5%</td>
<td>57.2%</td>
<td>60.2%</td>
<td>61.5%</td>
</tr>
<tr>
<td>CO2 emissions per sales (ton/¥ million)</td>
<td>0.67</td>
<td>0.66</td>
<td>0.66</td>
<td>0.67</td>
<td>0.66</td>
<td>0.67</td>
<td>0.66</td>
<td>0.66</td>
<td>0.66</td>
</tr>
<tr>
<td>Water usage (thousand m3)</td>
<td>18,721</td>
<td>19,768</td>
<td>19,768</td>
<td>18,721</td>
<td>19,768</td>
<td>19,463</td>
<td>19,768</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resource recycling rate (%)</td>
<td>98.3%</td>
<td>98.9%</td>
<td>99.5%</td>
<td>98.3%</td>
<td>98.9%</td>
<td>99.5%</td>
<td>98.3%</td>
<td>98.9%</td>
<td>99.5%</td>
</tr>
</tbody>
</table>

*1 Item names according to IFRS.
*2 SG&A expense under I-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 I-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 number of employees at Otsuka Holdings and its 162 subsidiaries (as of December 31, 2018).
*5 Number of employees at Otsuka Holdings and its 162 subsidiaries (as of December 31, 2018).
*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% of CO2 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 treatment, while the generation 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 85,395 million yen (down 25.3%) and profit attributable to owners of the Company of 85,395 million yen (down 25.3%).

Financial position
Assets
Total assets as of December 31, 2018 were 2,476,634 million yen, an increase of 51,590 million yen to 285,022 million yen at the end of the previous fiscal year. Current assets decreased by 77,840 million yen, while non-current assets were 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.

Liabilities
Total liabilities as of December 31, 2018 were 744,368 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.

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 profit before taxes, 18,456 million yen in profit attributable to owners of the Company, and 5,468 million yen in dividends.

Net 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 41,758 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 increased income tax refunds, 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 57,575 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 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, 41,758 million yen in repayments of non-current borrowings, and 55,295 million yen in dividends paid.
## Consolidated Statement of Financial Position

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

* 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$, the approximate exchange rate on December 31, 2018.

**Liabilities and equity**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current liabilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>¥ 159.9</td>
<td>¥ 170.9</td>
<td>$ 1,539</td>
</tr>
<tr>
<td>Bonds and borrowings</td>
<td>64.5</td>
<td>65.9</td>
<td>594</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>2.3</td>
<td>4.2</td>
<td>38</td>
</tr>
<tr>
<td>Income taxes payable</td>
<td>8.0</td>
<td>7.2</td>
<td>65</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td></td>
<td>10.8</td>
<td>97</td>
</tr>
<tr>
<td>Other current liabilities</td>
<td>151.7</td>
<td>168.5</td>
<td>1,518</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>386.5</td>
<td>427.5</td>
<td>3,851</td>
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<tr>
<td>Liabilities directly associated with assets held for sale</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>386.5</td>
<td>427.5</td>
<td>3,851</td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonds and borrowings</td>
<td>177.0</td>
<td>140.0</td>
<td>1,261</td>
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<tr>
<td>Other financial liabilities</td>
<td>19.0</td>
<td>22.8</td>
<td>206</td>
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<tr>
<td>Net defined benefit liabilities</td>
<td>14.7</td>
<td>18.3</td>
<td>165</td>
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<tr>
<td>Provisions</td>
<td>3.7</td>
<td>0.6</td>
<td>6</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td></td>
<td>87.2</td>
<td>786</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>44.7</td>
<td>35.6</td>
<td>320</td>
</tr>
<tr>
<td>Other non-current liabilities</td>
<td>12.8</td>
<td>13.3</td>
<td>111</td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td>271.8</td>
<td>316.9</td>
<td>2,855</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>658.3</td>
<td>744.4</td>
<td>6,706</td>
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<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity attributable to owners of the Company</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital</td>
<td>81.7</td>
<td>81.7</td>
<td>736</td>
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<tr>
<td>Capital surplus</td>
<td>505.6</td>
<td>505.9</td>
<td>4,558</td>
</tr>
<tr>
<td>Treasury shares</td>
<td>(47.3)</td>
<td>(47.3)</td>
<td>(426)</td>
</tr>
<tr>
<td>Retained earnings</td>
<td>1,266.4</td>
<td>1,229.4</td>
<td>11,075</td>
</tr>
<tr>
<td>Other components of equity</td>
<td>(13.2)</td>
<td>(65.2)</td>
<td>(587)</td>
</tr>
<tr>
<td><strong>Total equity attributable to owners of the Company</strong></td>
<td>1,793.3</td>
<td>1,704.5</td>
<td>15,356</td>
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<tr>
<td>Non-controlling interests</td>
<td>28.7</td>
<td>27.8</td>
<td>250</td>
</tr>
<tr>
<td><strong>Total equity</strong></td>
<td>1,822.0</td>
<td>1,732.3</td>
<td>15,606</td>
</tr>
<tr>
<td><strong>Total liabilities and equity</strong></td>
<td>¥ 2,480.3</td>
<td>¥ 2,476.6</td>
<td>$ 22,312</td>
</tr>
</tbody>
</table>
### Consolidated Statement of Income

<table>
<thead>
<tr>
<th></th>
<th>Billions of Yen</th>
<th>Millions of U.S.$*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017.12</td>
<td>2018.12</td>
</tr>
<tr>
<td>Revenue</td>
<td>¥1,240.0</td>
<td>$1,169.9</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(422.5)</td>
<td>(441.8)</td>
</tr>
<tr>
<td>Gross profit</td>
<td>817.5</td>
<td>850.2</td>
</tr>
<tr>
<td>Selling, general and administrative expenses</td>
<td>(508.7)</td>
<td>(564.4)</td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>(175.6)</td>
<td>(216.1)</td>
</tr>
<tr>
<td>Share of profit of associates</td>
<td>19.3</td>
<td>16.5</td>
</tr>
<tr>
<td>Other income</td>
<td>6.1</td>
<td>24.5</td>
</tr>
<tr>
<td>Other expenses</td>
<td>(4.4)</td>
<td>(2.3)</td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>104.2</td>
<td>108.3</td>
</tr>
<tr>
<td>Finance income</td>
<td>4.3</td>
<td>9.2</td>
</tr>
<tr>
<td>Finance costs</td>
<td>(5.1)</td>
<td>(8.0)</td>
</tr>
<tr>
<td>Other non-operating income (expenses)</td>
<td>0.3</td>
<td>0</td>
</tr>
<tr>
<td>Profit before taxes</td>
<td>103.7</td>
<td>109.5</td>
</tr>
<tr>
<td>Income taxes</td>
<td>10.7</td>
<td>(24.1)</td>
</tr>
<tr>
<td>Profit for the year</td>
<td>¥114.4</td>
<td>$85.4</td>
</tr>
</tbody>
</table>

* 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$, the approximate exchange rate on December 31, 2018.

### Consolidated Statement of Comprehensive Income

<table>
<thead>
<tr>
<th></th>
<th>Billions of Yen</th>
<th>Millions of U.S.$*</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2017.12</td>
<td>2018.12</td>
</tr>
<tr>
<td>Profit for the year</td>
<td>¥114.4</td>
<td>$85.4</td>
</tr>
</tbody>
</table>

* 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$, the approximate exchange rate on December 31, 2018.

### Consolidated Statement of Changes in Equity

<table>
<thead>
<tr>
<th></th>
<th>Billions of Yen</th>
<th>Millions of U.S.$*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017.12</td>
<td>2018.12</td>
</tr>
<tr>
<td>Balance as of January 1, 2017</td>
<td>¥36.9</td>
<td>$332</td>
</tr>
<tr>
<td>Restated balance</td>
<td>¥310.6</td>
<td>$2,765</td>
</tr>
<tr>
<td>Profit for the year</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Non-controlling interests</td>
<td>2 (0)</td>
<td>—</td>
</tr>
<tr>
<td>Share of profit of associates</td>
<td>3.6</td>
<td>2.1</td>
</tr>
<tr>
<td>Owners of the Company</td>
<td>135.3</td>
<td>137.8</td>
</tr>
</tbody>
</table>

* 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$, the approximate exchange rate on December 31, 2018.

** Note:** The table above provides a sample of the consolidated financial statements for Otsuka Holdings Co., Ltd. for the year ended December 31, 2018. Each statement is designed to provide a comprehensive overview of the company's financial performance and position. The U.S. dollar amounts are translations of the Japanese yen, and the exchange rate used is the approximate rate on December 31, 2018. The statements include revenue, operating income, profit and loss, changes in equity, and other relevant financial metrics. For a complete understanding, it is recommended to review the full report. The data is sourced from Otsuka Holdings Co., Ltd.'s Integrated Report 2018.
Creatively giving shape to the power of materials for customers and the future

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

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

A holistic healthcare company supporting whole-body health, from helping to cure disease

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

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Otsuka Group Corporate Philosophy

Otsuka—people creating new products for better health worldwide

Overview

The Otsuka group of companies, whose origins date back to 1901, 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 materials* business to support the maintenance and promotion of everyday health.

The company's culture, summarized in a few words as, “Hyakun-kako” (try we try to recognize the way), “Jishoku” (actualization) and “Saizetsu” (crescent), have been fostered by successive Otsuka leaders. These are embodied by our 47,006 employees across 189 group companies in 30 countries and regions who strive to create and market unique products and services.

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Organizational Structure

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Consolidated Financial Statements

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

Consolidated Statement of Cash Flows

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profit before taxes</td>
<td>¥ 103.7</td>
<td>¥ 109.5</td>
<td>$ 986</td>
</tr>
<tr>
<td>Depreciation and amortization expenses</td>
<td>62.2</td>
<td>59.3</td>
<td>534</td>
</tr>
<tr>
<td>Impairment loss and reversal of impairment loss</td>
<td>28.8</td>
<td>34.7</td>
<td>313</td>
</tr>
<tr>
<td>Share of loss (profit) of associates</td>
<td>(19.3)</td>
<td>(16.5)</td>
<td>(149)</td>
</tr>
<tr>
<td>Finance income</td>
<td>(4.3)</td>
<td>(9.2)</td>
<td>(83)</td>
</tr>
<tr>
<td>Finance costs</td>
<td>5.1</td>
<td>8.0</td>
<td>72</td>
</tr>
<tr>
<td>Other non-operating (income) expenses</td>
<td>(0.3)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Decrease (increase) in inventories</td>
<td>(8.4)</td>
<td>(17.4)</td>
<td>(157)</td>
</tr>
<tr>
<td>Decrease (increase) in trade and other receivables</td>
<td>(9.9)</td>
<td>(20.5)</td>
<td>(184)</td>
</tr>
<tr>
<td>Increase (decrease) in trade and other payables</td>
<td>(5.8)</td>
<td>16.3</td>
<td>147</td>
</tr>
<tr>
<td>Other</td>
<td>(12.3)</td>
<td>(6.3)</td>
<td>(59)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>139.5</td>
<td>157.7</td>
<td>1,421</td>
</tr>
<tr>
<td>Interest and dividends received</td>
<td>10.2</td>
<td>10.6</td>
<td>96</td>
</tr>
<tr>
<td>Interest paid</td>
<td>(3.6)</td>
<td>(3.0)</td>
<td>(27)</td>
</tr>
<tr>
<td>Income taxes paid</td>
<td>(43.2)</td>
<td>(29.6)</td>
<td>(267)</td>
</tr>
<tr>
<td>Net cash flows from (used in) operating activities</td>
<td>102.8</td>
<td>135.8</td>
<td>1,224</td>
</tr>
</tbody>
</table>

Cash flows from investing activities

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)    |
| Net cash flows from (used in) investing activities      | (40.1)  | (93.3)  | (841)   |

Cash flows from financing activities

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)    |
| Net cash flows from (used in) financing activities      | (94.5)  | (89.2)  | (804)   |

Increase (decrease) in cash and cash equivalents        | (31.8)  | (46.7)  | (421)   |

Cash and cash equivalents at beginning of period        | 369.9   | 336.6   | 3,033   |

Effect of exchange rate changes on cash and cash equivalents | (1.5)   | (4.9)   | (44)    |

Cash and cash equivalents at end of period               | ¥ 336.6 | ¥ 285.0 | $ 2,568 |

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Data Section

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018

Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2018
Global Network

Otsuka operates in 30 Countries and regions

Number of operations and employees

- Companies: 189
- Employees: 47,000
- Factories: 171
- Research Institutes: 47

History of global business expansion

- 1973: North America (U.S.)
- 1977: Africa (Egypt)
- 1979: Western Europe (Spain)
- 2006: China
- 2008: Eastern Europe (Czech Republic)
- 2012: Turkey
- 2015: Australia

Corporate Information/Shareholder Information

Corporate Profile (as of December 31, 2018)

- Company Name: Otsuka Holdings Co., Ltd.
- Established: July 8, 2008
- Capital: ¥ 81.69 billion
- Head Office: 2-9-Kanda-Tsukasamachi, Chiyoda-ku, Tokyo 101-0048, Japan
- Telephone: +81-3-6717-1410
- Number of Employees: 94 (consolidated: 32,935)
- Business: Description Control, management and related activities with respect to the Company's subsidiaries and affiliates in the pharmaceutical industry, nutraceutical industry, consumer products, and other areas.

Shares (as of December 31, 2018)

- Number of shares authorized: 1,600,000,000 shares
- Number of shares issued: 557,835,617 shares
- Number of shareholders: 54,112

Stock distribution

- Principal shareholders (top 10 shareholders)
  - Number of shares held: 10.66
  - Shareholding ratio (%): 57.798
  - Holdings: Shareholding Fund Trust Account

- Principal shareholders (other corporations)
  - Number of shares held: 36.61
  - Shareholding ratio (%): 23.202
  - Holdings: Shareholding Fund Trust Account

Company organization

- Board of Directors
  - Chairman
  - President
  - Statutory Auditor's Office
- Shareholders' Meeting
- Statutory Auditor's Office

Website information

Visit our website at:

https://www.otsuka.com/en/
Significance of the Corporate Symbol

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