Corporate Philosophy

Otsuka—people creating new products for better health worldwide

In keeping with this corporate philosophy and the Otsuka values of Ryukan-godo (by sweat we recognize the way), Jissho (actualization) and Sozosei (creativity), we strive to do what only Otsuka can do. 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 dynamic corporate culture and workplaces that reflect our vision as a healthcare company, to finding ways to live in harmony with local communities and the natural environment, and to contributing to richer and healthier lives.

What only Otsuka can do

Otsuka’s Goal

To become an indispensable contributor to people’s health worldwide

The Otsuka group aims to be an indispensable contributor to people’s health worldwide, fulfilling its corporate philosophy in every aspect of its operations. This commitment to improving people’s health worldwide is part of the unchanging value we will continue to provide society. 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.

* Nutraceutical = nutrition + pharmaceuticals
Providing Value through Our Businesses

The Otsuka group of companies contributes to people’s health worldwide by creating innovative products in its two core businesses: the Pharmaceutical Business, which aims to address unmet medical needs, and the Nutraceutical Business, which seeks to fulfill the yet-to-be-imagined needs of consumers.

Unmet medical needs
From diagnosis to treatment
Pharmaceutical Business

Yet-to-be-imagined needs
Maintaining and improving day-to-day health
Nutraceutical Business

Providing value
Bringing health to people worldwide
Total Healthcare

What only Otsuka can do

* The state of health, as defined in the constitution of the World Health Organization (WHO)
Otsuka’s History of Addressing Social Issues

Since its founding in 1921 as a chemical raw materials manufacturer, the Otsuka group has worked to address social issues by providing products that help realize healthcare that is aligned with society’s expectations, while responding to the changing times and business environment. The group has continued to grow while contributing to health in the three areas of physical, mental and social well-being. The year 2021 will be the centennial of our founding. Consistent with the aspirations of the company founders, we aim to offer products and services for the coming 100 years and into perpetuity, while helping to address future social needs.

Establishment of Major Group Companies

- **1921** Otsuka Seiyaku Kogyobu (now Otsuka Pharmaceutical Factory)
- **1950** Otsuka Chemical
- **1955** Otsuka Foods
- **1961** Otsuka Warehouse
- **1963** Taiho Pharmaceutical
- **1964** Otsuka Pharmaceutical
- **1967** Thai Otsuka Pharmaceutical
- **1973** Otsuka Indonesia
- **1974** Otsuka Pharmaceutical
- **1981** China Otsuka Pharmaceutical
- **1982** Korea Otsuka Pharmaceutical
- **1983** Calorie Mate
- **1984** Otsuka America
- **1985** Otsuka America Pharmaceutical
- **1988** Otsuka Pakistan
- **1989** Nature Made
- **1998** Otsuka Pharmaceutical Europe
- **2002** ABILIFY
- **2004** Taiho Pharmaceutical
- **2014** DELTYBA
- **2018** Nature Made
- **2021** Otsuka America Pharmaceuticals
- **2022** EQUELLE

### Changes in the Concept of Health

**Physical well-being**

**Mental well-being**

**Social well-being**

#### Intravenous Solutions

Otsuka’s intravenous solutions business began in Japan during the post-WW II period, when nutrition was a major issue for the nation. Otsuka pushed forward with technological innovations that met the needs of medical institutions, such as the development of Japan’s first plastic bottle for intravenous solutions. From the 1970s, using local production, we expanded the business to countries in Asia that were seeking to advance sanitary practices.

**1946**

The evolving IV solutions business

**1974**

Improving QOL for cancer patients

**Futrafal**

Launched by subsidiary Taiho Pharmaceutical as an oral anti-cancer agent at a time when such medicine was not widely used anywhere in the world. Unlike conventional anti-cancer agents at the time, Futrafal enabled outpatient treatment, making hospitalization unnecessary. Since then, Taiho Pharmaceutical has launched oral anti-cancer agents UFT, TS-1, and Lonsurf, and contributed to improved quality of life (QOL) for cancer patients.

**1980**

The importance of hydration becomes apparent

**POCARI SWEAT**

Inspired by the idea of a drinkable intravenous solution, POCARI SWEAT was developed as a beverage that could easily replenish fluids and electrolytes (ions) lost through perspiration. R&D progressed with the target of creating a health drink for everyday life, and in 1980, POCARI SWEAT was launched in Japan.

**1983**

Solving issues relating to irregular eating habits and unbalanced diets

**Calorie Mate**

Leveraging expertise in high-density liquid diets from our clinical nutrition business, we created Calorie Mate, which provides nutrition for healthy consumers. It supports healthy eating habits in busy modern lifestyles, and was a pioneer in nutritionally balanced foods in Japan. As the top-selling brand, it continues to lead the field.

* Source: Image SRI, nutritionally balanced food product market (category: cookies, biscuits, cereals and cakes), January–December 2019

**1989**

Supplementing nutrient deficiencies in food

**Nature Made**

In modern times, changes in lifestyles or eating habits can cause people to struggle at maintaining balanced diets. Even with careful meal planning, it can be difficult to obtain sufficient amounts of many nutrients. Supplementing meals with Nature Made products enables consumers to take in recommended amounts of such nutrients.

* Acquired Pharmavite of the U.S. in 1989, launched sales in Japan in 1993

### Pharmaceutical Business

**2002**

A new option for antipsychotic medications

**ABILIFY**

Diseases of the central nervous system (CNS) include numerous disorders. The underlying causes of these diseases have yet to be precisely elucidated, making the research and development of treatments extremely challenging. Antipsychotic agent ABILIFY was launched by Otsuka Pharmaceutical in the U.S. as the first therapeutic agent for the CNS developed through in-house drug discovery. On the basis of its unique characteristics, it has been well received by physicians and patients.

**2014**

Combating tuberculosis—an old disease with a new face

**DELTYBA**

Tuberculosis is an infectious disease that mankind has long fought to eradicate, and it remains a serious global health issue. As it is our duty to persevere where others have not, we have continued our research in this area. The culmination of more than 30 years of research, DELTYBA was approved as one of the world’s first new tuberculosis drugs in about half a century. It has now become an essential treatment for multidrug-resistant tuberculosis.
Otsuka's Strengths

What we can achieve because we are Otsuka

People are the source of our strengths. Since Otsuka's establishment in 1921, employees everywhere have pursued business guided by our enduring corporate philosophy in order to bring health to people worldwide. Through the determination of these employees, we have developed many strengths.

The six strengths described below are a representative sample, and more continue to evolve each day. Making the best possible use of these strengths, employees take on new challenges to fulfill our potential, all in order to contribute to better health worldwide.

- An enduring corporate philosophy and a managerial structure passed down and practiced throughout the group
- A business model centered on total healthcare
- An unwavering quest for originality
- A global reach incorporating solutions to social issues through our core business processes
- An ability to nurture enduring brands
- A solid financial foundation and strong earnings power, which drive sustainable growth

Value Creation Process That Generates Originality

Taking on the challenge of doing what only Otsuka can do

At the heart of the Otsuka group's value creation process is an approach that is always looking to the future in order to anticipate the various needs of healthcare aligned with society's expectations. We try to anticipate the diversifying needs that arise from the changing times, environment, and ways that people think about health. Then, leveraging our group strength of unique, wide-ranging businesses, and our people, who have extensive knowledge and experience, we construct hypotheses and combine new technologies and scientific developments with existing ones to create new value.

While working to resolve social issues we maximize the value we create (products and services). In that process, we capture new needs that emerge, which we harness in turn to create more new value.

Sustainable growth of the Otsuka group through this value creation process leads to steady enhancement of corporate value, while also making it possible for us to continue applying our original approach to the challenge of new healthcare needs.
Realizing a Sustainable Society

Value Creation Model

Otsuka’s Strengths ➔ Page 6
What we can achieve

Business Strategy
Medium-Term Management Plan

Value Creation Process That Generates Originality ➔ Page 7
What only Otsuka can do

Value Creation Model

Management Resources
Supporting the Otsuka Group

Human Capital
Employees: 47,000*
Japan: 18,000
Outside Japan: 29,000

Relationship and Social Capital
Total Group companies: 195
Japan: 50
Outside Japan: 145
Locations: 31 countries/regions

Manufactured Capital
Manufacturing sites: 173
Japan: 53
Outside Japan: 120

Intellectual Capital
Research sites: 49
Japan: 24
Outside Japan: 25

Financial Capital
Total assets: ¥2,581.3 billion

Natural Capital
Total Group companies: 195
Japan: 50
Outside Japan: 145
Locations: 31 countries/regions

People, Environment, Corporate Governance, Compliance, Risk Management

Corporate Philosophy
Otsuka-people creating new products for better health worldwide

* Data for 195 companies including Otsuka Holdings and its subsidiaries and affiliated companies (as of December 31, 2019)
In 2019, the Otsuka group determined material issues based on their importance to society and to the group’s businesses.

**Process for Determining Material Issues**

To determine the Otsuka group’s material issues, we first compiled a list of social issues, referencing a range of international guidelines and frameworks, including ISO 26000, GRI, and the U.N. SDGs. We narrowed down the list of issues by evaluating them in terms of their importance, taking into account our ability to contribute to a solution, their impact on business, and our strengths. Issues were then discussed by the CSR Promotion Committee and approved at the Otsuka Holdings Board of Directors meeting. As a result, the material issues of the Otsuka group were determined to be: Society (Health, People, Quality in All We Do), Environment (Climate Change, Resource Recycling and Conservation, Water Conservation), and Governance.

1. The CSR Promotion Committee promotes CSR throughout the Otsuka group. The committee’s responsibilities include discussing and deciding on the direction and plans for CSR activities. The Otsuka Holdings director in charge of CSR promotion serves as the committee chair. Committee members consist of regional group managers involved in CSR and the CSR officers of each company.

2. Our nine highly important material issues are indicated in bold.

3. The situation where productivity does not go up due to the poor condition of the mind and body despite coming to work.

4. Fragile governance system

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**Map of Social Issues**

<table>
<thead>
<tr>
<th>Social Issues</th>
<th>Our Goals</th>
<th>Our Activities</th>
<th>Related SDGs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>Unmet medical and health needs</td>
<td>Contribute to unmet needs solutions</td>
<td>Promotion of R&amp;D for unmet needs</td>
</tr>
<tr>
<td></td>
<td>Spread of infectious diseases</td>
<td>Eradication of tuberculosis</td>
<td>R&amp;D of tuberculosis drugs and improvement of drug access</td>
</tr>
<tr>
<td></td>
<td>Nutritional needs</td>
<td>Creation of a system for the realization of a healthful life</td>
<td>Support and awareness activities for people’s health</td>
</tr>
<tr>
<td></td>
<td>Increasing aging issues</td>
<td>Healthy life extension</td>
<td>Promotion of problem solving by strengthening partnerships</td>
</tr>
<tr>
<td>Society</td>
<td>Consumption and production that impairs sustainability</td>
<td>Gaining stakeholder trust</td>
<td>Sustainable procurement and product design</td>
</tr>
<tr>
<td></td>
<td>Unprepared for diversification</td>
<td>Pursuing sustainability at all levels of the value chain</td>
<td>Thorough quality control and management</td>
</tr>
<tr>
<td></td>
<td>Establishing a quality assurance system for safety and security</td>
<td>Establishing a quality assurance system for safety and security</td>
<td>Responsible promotional activities and information provision</td>
</tr>
<tr>
<td></td>
<td>Fragile governance system</td>
<td>Supporting stakeholders</td>
<td>Deepening communication with stakeholders</td>
</tr>
<tr>
<td></td>
<td>Reducing freshwater availability</td>
<td>Promotion of “customer-centric management”</td>
<td>Promotion of “customer-centric management”</td>
</tr>
<tr>
<td>Climate Change</td>
<td>Global warming</td>
<td>FY 2030 Goal: 30% reduction in CO2 emissions compared to FY 2017</td>
<td>Reduce CO2 emissions throughout the value chain</td>
</tr>
<tr>
<td>Environment</td>
<td>Environmental load increase</td>
<td>FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019</td>
<td>Reduce environmental impact by improving resource efficiency</td>
</tr>
<tr>
<td></td>
<td>Reducing freshwater availability</td>
<td>FY 2030 Goal: 50% or higher content of recycled and plant-based materials in our PET bottles</td>
<td>Promotion of business activities aimed at a sustainable state in both society and the earth</td>
</tr>
<tr>
<td>Resource</td>
<td>Global warming</td>
<td>FY 2030 Goal: 50% reduction in CO2 emissions compared to FY 2017</td>
<td>Understanding water resources risk</td>
</tr>
<tr>
<td>Recycling</td>
<td>Environmental load increase</td>
<td>FY 2030 Goal: 50% or higher content of recycled and plant-based materials in our PET bottles</td>
<td>Management and effective use of water resources</td>
</tr>
<tr>
<td>Governance</td>
<td>Unmet medical and health needs</td>
<td>Contribute to unmet needs solutions</td>
<td>Strengthening corporate governance</td>
</tr>
<tr>
<td></td>
<td>Spread of infectious diseases</td>
<td>Eradication of tuberculosis</td>
<td>Thorough compliance</td>
</tr>
<tr>
<td></td>
<td>Nutritional needs</td>
<td>Creation of a system for the realization of a healthful life</td>
<td>Risk identification, evaluation and management</td>
</tr>
</tbody>
</table>
### Initiatives for Sustainability

From among the 12 social issues we determined to be the Otsuka group’s materialities, we selected 9 that we currently regard as highly important, and set goals related to them for fiscal 2023.

<table>
<thead>
<tr>
<th>Materiality</th>
<th>Social Issues</th>
<th>Our Goals</th>
<th>FY 2023 Goals</th>
<th>FY 2019 Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>Unmet medical and health needs</td>
<td>• Contribute to unmet needs solutions</td>
<td>• Promotion of R&amp;D for unmet needs</td>
<td>• Maintained ratio of R&amp;D expenses to revenue in Pharmaceutical Business of at least 20% for three consecutive years (Page 68, Financial and Non-Financial Highlights)</td>
</tr>
<tr>
<td></td>
<td>• Spread of Infectious diseases</td>
<td>• Eradication of tuberculosis</td>
<td>• Provide DELTAMBA (generic name: delamanid) for a cumulative total of 60,000 cases</td>
<td>• Expanded countries/regions where DELTAMBA is available to over 100</td>
</tr>
<tr>
<td></td>
<td>• Nutritional needs</td>
<td>• Creation of a system for the realization of a healthyful life</td>
<td>• Create new systems and reinforce existing systems for realizing healthy lifestyles</td>
<td>• U.S. National Institutes of Health (NIH) launched a large-scale clinical trial to confirm the preventive efficacy of delamanid for multidrug-resistant tuberculosis (Continued participation in the Global Health Innovative Technology Fund (GHTF Fund))</td>
</tr>
<tr>
<td>People</td>
<td>Unprepared for diversification</td>
<td>• Creation of a corporate culture that stimulates creativity</td>
<td>• Further instill the corporate culture and philosophy</td>
<td>• Executed cooperation agreements with all 47 prefectures and promoted collaboration in health and other fields (Continued to hold Women’s Health Seminar)</td>
</tr>
<tr>
<td></td>
<td>• Consumption and production that impairs sustainability</td>
<td>• Pursue sustainability at all levels of the value chain</td>
<td>• Companies implementing SAQ2: 200</td>
<td>• Cumulative total participants in executive human resource development programs of Otsuka Global Academy: 141</td>
</tr>
<tr>
<td>Quality in All We Do</td>
<td></td>
<td></td>
<td></td>
<td>• Cumulative total participants in Health Seminars: 1,050</td>
</tr>
<tr>
<td>Environment</td>
<td>Global warming</td>
<td>• FY 2030 Goal: 30% reduction in CO2 emissions compared to FY 2017</td>
<td>• Introduce renewable energy and raise usage rate of CO2-free-electricity</td>
<td>• Cumulative total of companies implementing SAQ: 34</td>
</tr>
<tr>
<td></td>
<td>• Environmental load increase</td>
<td>• FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019</td>
<td>• Set group environmental goals</td>
<td>• Held global production meetings and environmental management information exchange meetings</td>
</tr>
<tr>
<td></td>
<td>• Reducing freshwater availability</td>
<td>• FY 2030 Goal: 50% or higher content of recycled and plant-based materials in our PET bottles</td>
<td>• Standardized and tracked global data on waste recycling volume</td>
<td>• Held global product quality meetings</td>
</tr>
<tr>
<td>Governance</td>
<td>Social change risk</td>
<td>• Long-term improvement of corporate value</td>
<td>• Strengthen corporate governance to further raise effectiveness</td>
<td>• Carried out water risk assessments using Aquapoll2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Build a governance system capable of global business development and response to various changes</td>
<td>• Conducted water use questionnaires and clarified issues at each production site</td>
</tr>
</tbody>
</table>

1. Unmet needs area defined by Otsuka based on PatientsMap2018US, PatientsMap2019JP, M3 & SSRI
2. Otsuka Advanced Training for Healthy Supporter: A program that supports pharmacies as health information hubs with strong connections to local communities
3. CO2 procurement self-assessment questionnaire
4. Aquapoll2 Water Risk Atlas: A water risk mapping tool developed by the World Resources Institute
The Otsuka group of companies will contribute to society while achieving sustained growth by doing what only Otsuka can do.

Under our enduring corporate philosophy “Otsuka—people creating new products for better health worldwide,” the Otsuka group of companies creates innovative products that fulfill a universal human desire to be healthy.

The core of our management approach is to leverage our strengths and capabilities described on the following pages that enable us to do what only Otsuka can do. In doing so, we are also contributing to, and advancing, a sustainable society. As we stand at a juncture of ever-larger social change, our philosophy serves as a solid foundation, guiding us amidst the trends and tides of the times, and from which we take on new challenges and opportunities.

Q1. What is the Otsuka group’s long-term vision?

We create and provide a comprehensive portfolio of products and services that meet the specific healthcare needs of the times in each community. Factors that influence these needs include the emergence of new disease trends, and demographic trends such as aging populations and rates of population growth that are uneven around the world. Simultaneously, factors that influence the ability to address these needs include the evolution of gene therapies, an area that Otsuka is investing in; artificial intelligence; and other technologies. Becoming an indispensable contributor to people’s health worldwide requires us to anticipate society’s expectations in 10 and 20 years’ time.

What kind of contributions can our Pharmaceutical Business make? As populations continue to age, treatments, or better yet, preventions are needed for diseases such as Alzheimer’s disease and various forms of cancer. At the same time, infectious diseases such as tuberculosis will become even more pressing global challenges. At the other extreme, many hereditary, orphan diseases lack any treatments. Otsuka is contributing through research in many of these disease areas. For COVID-19, contributions by our group companies around the world have mainly taken the form of philanthropy. Simultaneously, maintaining and improving health is an integral part of our Nutraceutical Business. Otsuka continues to invest in research that clarifies how people can maintain a healthy lifestyle and thereby avoid illness. A fundamental demand driver for nutraceutical products is people’s greater proactivity in managing their health across their entire lifespans. This includes, for example, women who balance professional and family demands, athletically minded people aiming to improve their overall fitness and stamina, and older people seeking extended quality-of-life benefits. Our contribution in nutraceuticals also takes a research-based approach. Here the aim is to create products that offer tangible, health-supportive benefits in areas such as immune function, quality of sleep, and special dietary needs, and even intangible benefits that support individual lifestyles and work styles. Given the time required for product development, we must construct hypotheses that look 10 and 20 years into the future, and start developing products now.

Q2. What business risks and opportunities do you see in the long term?

Changes in human needs, and in business and other landscapes are the largest sources of risk and opportunity. Risks that our management factors into decision making include macroeconomic and geopolitical climates; the physical climate, with increasingly frequent natural disasters caused in part by global warming; and demographic changes. In order to devise optimal responses or solutions, we must identify root causes. On the opportunity side, this involves evolution of product development and technologies, expansion of our presence in new regions, and the forging of new research and commercial collaborations. Focusing our energies on opportunities, while managing but not being overwhelmed by risks, is the right approach for Otsuka.

As a total healthcare company, our operations encompass products and services for the diagnosis and treatment of diseases, as well as for the maintenance and improvement of health. Medical cost inflation due to aging populations and the increasing sophistication of medical treatment is a serious global issue. As a provider of total healthcare solutions, we recognize these developments as responsibilities and opportunities. Our diverse portfolio enables us to turn risks into opportunities.

Q3. What does Otsuka need to do to improve corporate value while achieving sustainable growth?

In keeping with our corporate philosophy and our long-standing ESG-informed commitment to contributing to human health, we set forth our CSR Mission when we announced the Third Medium-Term Management Plan in May 2019. The CSR Mission defines material issues in three categories: Society (Health, People, Quality in Air We Do), Environment (Climate Change, Resource Recycling and Conservation, Water Conservation), and Governance. Within each category, we carry out initiatives under related themes.
We leverage these together with other advantages of our wide-ranging businesses—such as a diverse wealth of technological and scientific assets—to create novel ideas and ultimately new value. In this way, the Otsuka group is able to help society achieve sustainable growth, increase corporate value over the medium to long term, and ultimately make its vision a reality—to become an indispensable contributor to people's health worldwide.

Q5. What will be essential to Otsuka's further development?

In order to better recognize where we stand and what we strive for, we must continually question ourselves from the perspectives of Strategy, Culture, and Capabilities. Strategy is closely tied to our corporate philosophy, which guides our thinking because it is the very foundation of our business strategy, and is an expression of our determination to constantly take on new challenges and generate innovation.

Culture is best defined by the words of our founders, Ryukan-godo, Jissho and Sozosei. Companies with a solid philosophical foundation are the strongest in turbulent times. Our ability to embrace change and continually take on new challenges is not down to individual leaders acting alone, but to generations of employees who have been inspired by our founders. Upholding this strategy and culture takes formidable Capabilities, and each individual must constantly review what he or she is capable of and swiftly address deficiencies.

Q6. How do you ensure engagement with Otsuka’s philosophy and approach among employees around the world?

We believe that an effective way to instill our philosophy is to share stories of our successes, and failures along the way. Stories, in other words, through communication grounded in experience and fact. Philosophies and approaches cannot be shared properly in the abstract alone; they must be accompanied by concrete examples. Take, for instance, the development of Saxenda/DYNABOLQ,
1 the first-in-the world therapy for ADPKD.2 It took more than ten years to conduct phase III trials in the U.S., but it has since grown into our next blockbuster product following ABILIFY, with overall global brand sales exceeding one billion U.S. dollars in 2019. A concrete example like this inspires a better understanding of how Otsuka’s innovation contributes to people’s health. Generating engagement with Otsuka’s philosophy and culture through our successes has brought us to where we are today, and will build the Otsuka of tomorrow.

Otsuka will celebrate its 100th anniversary in 2021. This is an ideal opportunity for group companies in Japan and around the world to deepen employee understanding of Otsuka’s philosophy and approach as we prepare to embark on another century of success. 1. Brand name for ADPKD treatment in multiple regions outside Japan 2. Brand name for ADPKD treatment in the U.S. 3. Autosomal dominant polycystic kidney disease

Q4. Can you describe the Otsuka group's value creation model and its contribution to a sustainable society?

Guided by our corporate philosophy “Otsuka-people creating new products for better health worldwide,” and our essence of management—Ryukan-godo, Jissho and Sozosei—we seek to demonstrate our unique capabilities and achieve our unique potential, thereby contributing to the realization of a sustainable society and stable growth.

Six strengths underlie our success: 1) An enduring corporate philosophy and a managerial essence, passed down and practiced throughout the group; 2) a business model centered on total healthcare; 3) an unwavering quest for originality; 4) a global reach incorporating solutions to social issues with our core business processes; 5) an ability to nurture enduring brands; and 6) a solid financial foundation and strong earnings power, which drive sustainable growth.

Also, our value creation process enables Otsuka to do things that other companies cannot. First, we seek to anticipate emerging needs from the broad consumer and patient populations who use our products, as well as needs arising from the evolving environments around the world where we do business.

For Society, we focus on human resources. In order to achieve sustainable growth, continuous improvement of capabilities as individuals, teams, and organizations is required in addition to management principles and corporate culture. We recognize employee growth as an important management issue. To that end, Otsuka Holdings launched the executive human resource development programs of the Otsuka Global Academy in 2016 to foster human resources capable of driving future growth. Three programs are offered to group employees. The Senior Leadership Program and Middle Leadership Program are designed to nurture management candidates, while the Global Leadership Program, launched in 2019, is fostering a global managerial cadre comprised of employees from around the world.

Each group company is also actively involved in human resource development. For instance, Otsuka Pharmaceutical has operated WING, a voluntary leadership study group, since 2009. Participants identify internal and external issues, and work in teams to discuss potential solutions before formulating a proposal for consideration. At Taiho Pharmaceutical, “Global One Academy” was established in 2016. In addition to individual growth, we believe that diversity is vital. The variety of innate qualities that individuals bring to our teams is important to us, and we actively welcome people of all nationalities, races, ages, genders, and abilities, in the belief that breaking down barriers to inclusion is the key to sparking innovation and furthering our globalization.

For Environment, our initiatives focus on sustainability throughout the supply chain. We have been steadily implementing various measures, which in 2019 included the introduction of CO2-free electricity and co-generation systems. Moreover, in response to the pressing issue of plastic usage and subsequent pollution, we issued the Otsuka Group Plastic Policy, which defines goals for achievement by 2030, and are undertaking group-wide initiatives. For Governance, we have built a framework in which four of 13 directors are outside directors, and three of four Audit & Supervisory Board members are outside auditors (as of April 2020). Our outside directors are: Yukio Matsutani, who has extensive experience in, and deep insights into, the medical welfare field; Ko Seguchi, who has extensive management experience and high-level expertise in the pharmaceutical industry; Yoshisasa Aoki, who has extensive management experience and deep expertise in the food industry; and, starting this year, Mayo Mita, who is highly knowledgeable regarding finance and markets. The diverse experience and expertise of these outside directors complements the knowledge and skills of the nine inside directors, and together they form an effective governance body, capable of vigorous discussion.

The sheer number of companies in the Otsuka group means that effectively managing our subsidiaries in Japan and around the world necessitates a different approach from a single-purpose company. Such management requires oversight with detailed knowledge of each company's business. We are also working to solidify the management platform underpinning our global operations through standardization and better efficiencies, including expansion of shared services and optimization of procurement. In addition, we are strengthening internal control functions to ensure disciplined management. Enhancing management functions can have an impact that amplifies across the organization to boost corporate value.

In 2019, a concrete example like this inspired a better understanding of how Otsuka’s innovation contributes to people’s health. Generating engagement with Otsuka’s philosophy and culture through our successes has brought us to where we are today, and will build the Otsuka of tomorrow.

Otsuka will celebrate its 100th anniversary in 2021. This is an ideal opportunity for group companies in Japan and around the world to deepen employee understanding of Otsuka’s philosophy and approach as we prepare to embark on another century of success.

1. Brand name for ADPKD treatment in multiple regions outside Japan 2. Brand name for ADPKD treatment in the U.S. 3. Autosomal dominant polycystic kidney disease
Targeting sustainable growth and increased corporate value, we will enhance our cash flow generation and capital efficiency through optimal resource allocation.

Yuko Makino
Executive Director, CFO
Otsuka Holdings Co., Ltd.

Business Management with a Corporate-wide Awareness of Capital Cost

The Third Medium-Term Management Plan is positioned as a period for adopting business management with a corporate-wide awareness of capital cost under a strategy of maximizing existing business value and creating new value. We will promote this approach throughout the group as we target sustainable growth.

While we already consider cost of capital in deciding on individual investments or recognizing impairment losses, we included “business management with a corporate-wide awareness of capital cost” in the Third Medium-Term Management Plan so as to instill a broad awareness of cost of capital throughout the group, not just as it relates to individual investments. This will lead to sustainable, more effective cash flow generation and greater investment efficiency.

Under the Second Medium-Term Management Plan, we pursued a policy of active strategic investment using revenues from growing global sales of ABILIFY, and succeeded in diversifying our revenue structure. Furthermore, given that looming patent expirations were a major management issue, we executed this diversification with a focus on securing sufficient cash returns from financial institutions when necessary.

We are applying ROIC to maximize investment efficiency, with a group-wide target of at least 1.0% above the cost of capital (5.5%). On the other hand, contributing to society through ongoing innovation is important to us, so if investments that include a certain amount of risk are aligned with the group’s corporate philosophy or are conducive to sustainable growth, then we will continue to take on these challenges.

To implement this stance, we believe a comprehensive group-wide financial framework is essential. It must be based on steady cash flow generation from existing assets, and other measures that include issuing bonds and commercial paper or borrowing from financial institutions when necessary.

A Financial Framework Conducive to Improving Medium-to-Long-Term Corporate Value

Maximizing Existing Business Value and Creating New Value

We will secure operating cash flows through organic business growth, reinvest in growth areas and distribute returns to shareholders, while maintaining an appropriate level of financial leverage. Furthermore, we will establish a framework that achieves returns from reinvested capital in excess of the cost of capital, which will drive profit growth, and in turn enable us to make further growth investments and enhance shareholder returns.

Cash Flow Allocation Policy

We will balance the allocation of cash flows between prioritizing growth investments aimed at generating ongoing increases in medium-to-long-term returns in excess of cost of capital, and delivering stable shareholder returns.

For growth investments, we will consider investments that have synergy with existing management assets to generate greater value. In the Pharmaceutical Business, our main investments will be aimed at enhancing our products and pipeline in the psychiatry and neurology, oncology, and cardiovascular and renal areas. In the Nutraceutical Business, we will actively invest in new businesses that meet society’s future needs.

Our basic policy for shareholder returns is to maintain stable dividends. While emphasizing the continuity and stability of dividends, we will consider additional shareholder returns depending on profit growth, applying a comprehensive approach to securing sufficient cash returns, to pursue growth investments, a solid financial standing and the optimal capital structure.
History

Raising Awareness of Heat Disorders and the Importance of Replenishing Fluids and Electrolytes

Founded as a chemical raw material manufacturer in 1921, the Otsuka group launched its intravenous solutions business in 1946. Leveraging expertise cultivated in the intravenous solutions business, we developed POCARI SWEAT as a beverage that replenishes the body’s fluids and electrolytes, which are important for maintaining and improving day-to-day physical health. Later, in 1992, we participated in the Japan Amateur Sports Association (now Japan Sport Association (JSPO)) Study Group for Prevention of Heat Disorders in Sports Activities, and began full-fledged activities to raise awareness of heat disorders and their prevention. Since then, we have used scientific evidence to raise awareness of the importance of fluid and electrolyte replenishment in various aspects of life.

This brings us to the present day. The pathology of heat disorders, which was not well known in those early days, and the concept of supplying electrolytes together with fluids as a countermeasure, are now widely understood and recognized throughout society. POCARI SWEAT has become a popular staple in all kinds of situations where people sweat, including sports, commuting, outdoor work, and after a bath or waking up. Today, we continue to promote awareness of the importance of replenishing fluids and electrolytes in various contexts, including children’s sports activities, occupational safety and hygiene, and hydration for the elderly.

POCARI SWEAT is a health beverage that easily replenishes the body with fluids and electrolytes lost due to perspiration. When people sweat to regulate their body temperature, they lose electrolytes along with fluids. Just drinking water may upset the balance between fluids and electrolytes, which can negatively affect physical condition and performance. Proper hydration is necessary. As a beverage that is similar to fluids already present in the human body, POCARI SWEAT enables efficient fluid replenishment.

1. One unit equals 340 ml; units sold includes overseas sales

1980
Launched in Japan

1982
First overseas market entry

1987
Cumulative units sold: 3 billion

1993
Cumulative units sold: 10 billion

1998
Cumulative units sold: 20 billion

2008
Cumulative units sold: 30 billion

2020
40th anniversary

Supplying quality fluids and electrolytes to people all around the world

1992
Began cooperation with Japan Amateur Sports Association’s Study Group for Prevention of Heat Disorders in Sports Activities

2. Now Japan Sport Association (JSPO)

1993

2007
Began cosponsoring production of a guidebook on heat disorder prevention, based on the Guidelines for Prevention of Heat Disorders in Everyday Life (Ver. 1) published by the Japan Society of Biometeorology

2007
Conducted lectures on hydration for 500,000 members of junior sports clubs nationwide as part of the Sports Activities Campaign

2010
Commenced activities at public and other health centers across Japan to raise heat disorder awareness among seniors

2012
Began Live On Seminar as a lecture for industrial physicians and public health nurses, nurses, nutritionists, and health and safety staff working at business offices in Japan

2012
Co-sponsored production of the Heat Disorders Prevention website (NPO Weather Caster Network)

2016
Received Best Communicator and Top Runner Award at the Heatstroke Prevention Communication Project Hitosuzumi Awards 2016

2017
Participated in the reprinting of the Ministry of the Environment’s Environmental Health Manual on Heat Disorders
Otsuka Pharmaceutical’s Saga Nutraceuticals Research Institute gathers various kinds of evidence through clinical trials on the replenishment of fluids and electrolytes under various conditions.

In 2018, leveraging our expertise from research into heat disorders, we launched POCARI SWEAT ICE SLURRY. We developed this product using proprietary technology for creating a formulation that freezes in the form of ice slurry (in which solid particles are dispersed in a liquid), which is known for its high cooling properties. This “drinkable ice” efficiently cools the body from its core, and offers people a new option for combating heat disorders when active in hot environments.

Otsuka Pharmaceutical Ion Supply Drink Research Lab

Sales countries/regions: More than 20
Production countries/regions: 6 sites

Replenishing fluids and electrolytes lost through perspiration around the world

Two years after its launch in Japan, POCARI SWEAT made its overseas debut in 1982. At present, it is sold in more than 20 countries/regions.

Present
Why POCARI SWEAT Continues to Create New Value

Situations in which the body becomes dehydrated are various, and are not limited to any particular time or place. Otsuka Pharmaceutical’s marketing of POCARI SWEAT includes activities to raise awareness of the importance of hydration in more than 20 countries/regions around the world. POCARI SWEAT continues to create new value—meeting the challenge of changes in the environment and people’s values, and social diversification. This is because POCARI SWEAT continues to be closely intertwined with people’s lives, and to uncover and address underlying issues. As a science-based solution for universal needs, it generates value that leads to better health and better lifestyles.

Future
The World POCARI SWEAT Aims to Create

Global warming is having a major worldwide impact on climate and the natural environment, as well as people’s lives. Should global warming continue, as many as 1.2 billion people could be at risk of heat disorders every year by the year 2100. Also, it is estimated that due to the expansion of habitats conducive to the propagation of organisms that carry tropical diseases, including Zika fever and dengue fever, the number of people at risk of infection could increase by 383–725 million by 2050.* Meanwhile, the importance of and proper methods for fluid and electrolyte replenishment as “first aid” for heat disorders and tropical disease infection have not yet become globally recognized.

We explore and identify underlying issues in each country, consider solutions, convey the scientific grounds and encourage consumers to try POCARI SWEAT. Through simple measures such as these, we contribute to the health of people worldwide. Fluids and electrolytes are essential to life. Our vision is to use our enduring spirit of inquiry and our ability to flexibly address the needs of a diversifying society to make POCARI SWEAT a health beverage like no other.

Around the world, there are many people who have difficulty maintaining their health because they lack access to a quality source of hydration. POCARI SWEAT aims to change the world by being an industry leader and contributing to solving social issues.

* Daniel Lu et al., Environ Res Lett 2020

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Otsuka Pharmaceutical Ion Supply Drink Research Lab

https://www.otsuka.co.jp/en/nutraceutical/about/rehydration/researchlab/
Positioning of the Third Medium-Term Management Plan

Advance in the Global Market as a Unique Total Healthcare Company—Five-Year Growth Phase (2019–2023)—

Existing Business Value Maximization and New Value Creation

Performance Target: Business Profit CAGR of 10% or More

- Organic growth of mainstay products and brands in Pharmaceutical and Nutraceutical Businesses
- Actively invest in R&D to continue creating new drugs that will drive revenue during and beyond the next medium-term management plan

Business Strategy: Existing Business Value Maximization and New Value Creation

Strategic initiatives for mainstay products and brands to accelerate growth.
- Strengthen strategic initiatives for growth drivers—4 Global Products in the Pharmaceutical Business; 3 Major Brands and 3 Nutraceutical Brands in the Nutraceutical Business
- Initiatives for next-generation businesses and products

Launch and nurture new drivers for sustainable growth in Pharmaceutical and Nutraceutical Businesses

Business Strategy Section

Social Issues Relating to Strategies, and KPIs

Social Issue Strategic Theme KPIs in the Third Medium-Term Management Plan

<table>
<thead>
<tr>
<th>Social Issue</th>
<th>Strategic Theme</th>
<th>KPIs in the Third Medium-Term Management Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmet medical and health needs</td>
<td>Existing Business Value Maximization</td>
<td>Revenue from 4 Global Products: Increase by ¥100 billion</td>
</tr>
<tr>
<td>Generate Innovation From Creative and Diverse Research Platforms</td>
<td>Challenge New Frontiers: Do what only Otsuka can do</td>
<td>Revenue from New Products: Increase by ¥50 billion</td>
</tr>
<tr>
<td>Generate Innovation From Creative and Diverse Research Platforms</td>
<td>Generate Innovation From Creative and Diverse Research Platforms</td>
<td>Projects to be filed for regulatory approval</td>
</tr>
<tr>
<td>Nutritional needs</td>
<td>Challenge New Categories and New Areas</td>
<td>Projects to be filed for regulatory approval</td>
</tr>
<tr>
<td>Nutritional needs</td>
<td>Continuous High Profit Structure</td>
<td>Fiscal 2023 business profit margin of Nutraceutical Business: 14.4%</td>
</tr>
</tbody>
</table>

Linking Investments and Results

Across our entire value chain, we are investing in anticipation of changes and issues five to ten years in the future, and working to steadily generate results from those investments.

A. 4 Global Products driving the group’s growth

To maximize the value of our 4 Global Products—ABILIFY MAINTENA, REXULTI, Samsca/INJURY/NIQUE, and Lonsurf—we continued to invest for growth, including signing a joint development and sales agreement with Lundbeck for ABILIFY MAINTENA and REXULTI, establishing an in-house development and sales system in the U.S. oncology business, and signing a European licensing contract with Servier for Lonsurf. As a result, these products are now driving the group’s growth.

B. Accelerating collaborations among Otsuka Pharmaceutical, Taiho Pharmaceutical and Astex Pharmaceuticals

We are sharing proprietary cutting-edge technologies cultivated by each operating company.

C. Diversification of drug discovery modalities

With a focus on generating innovation from creative and diverse research platforms, we plan to diversify drug discovery modalities and strengthen our in-house drug discovery platforms mainly by collaborating with and acquiring organizations with innovative and highly original drug discovery technologies.

Business Nutritional needs

Nutraceutical Business: Grow revenue to ¥500 billion or more, achieve business profit margin of 10% or higher

Pharmaceutical Business

First Medium-Term Management Plan

- Executed a global alliance agreement with Lundbeck in the MINI and MICRO areas
- Established Taiho Ventures
- Acquired Visterra, including rights to its antibody platform technology

Second Medium-Term Management Plan

- Acquired Daiya Foods
- Acquired BC BIO
- Acquired Jasmine

Third Medium-Term Management Plan

- Established strategic collaboration in the oncology area with Taiho Pharmaceutical, Astex Pharmaceuticals and MSD—A
- Executed a development and sales agreement for vadadustat with Taiho Pharmaceutical
- Executed a comprehensive cooperation agreement with the Japan Kidney Association for ADPKD and a business agreement for the alternative treatment of uremic encephalopathy
- Established a partnership between Taiho Pharmaceutical and Fujisawa Healthcare
- Executed a joint research agreement with PhoreMost—C

Taking on challenges in new areas

- Strengthening infrastructure for group collaborations in the oncology area
- Taking on challenges in new regions
- Established a new health beverage subsidiary in Myanmar

Taking on challenges in new regions

- Established a new health beverage subsidiary in Mexico
- Established the Honduran Waka Waka, a new high-performance drinking water facility
Progress of the Third Medium-Term Management Plan

Overview of Fiscal 2019

In fiscal 2019, the first year of the Third Medium-Term Management Plan, we steadily executed priority measures aimed at maximizing existing business value. As a result, revenue was 1,396.2 billion yen, an increase of 8.1% from the previous year, indicating solid growth. Furthermore, business profit was 187.2 billion yen, a substantial increase of 54.8% from the previous year, outperforming the Third Medium-Term Management Plan forecast for the year.

Revenue in fiscal 2019 rose 34.9% from the previous year, indicating solid growth. Furthermore, business profit was 187.2 billion yen, a substantial increase of 54.8% from the previous year, outperforming the Third Medium-Term Management Plan forecast for the year.

| Revenue Plan for the 4 Global Products and New Products
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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Plan period</td>
<td>2018A</td>
<td>2019A</td>
<td>2020E</td>
</tr>
<tr>
<td>(¥ billion)</td>
<td>1,292.0</td>
<td>1,396.2</td>
<td>1,445.0</td>
</tr>
<tr>
<td>Business profit</td>
<td>1,560.0</td>
<td>1,700.0</td>
<td>1,600.0</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>390.0</td>
<td>460.0</td>
<td>415.0</td>
</tr>
<tr>
<td>Business profit</td>
<td>160.0</td>
<td>200.0</td>
<td>150.0</td>
</tr>
<tr>
<td>ROE</td>
<td>7.3%</td>
<td>8.0%</td>
<td>8.0%</td>
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The Third Medium-Term Management Plan calls on us to maximize existing business value and create new value, to challenge new frontiers by doing what only Otsuka can do, and to generate innovation from creative and diverse research platforms. We will take advantage of this strategic framework to position our 4 Global Products—ABILIFY MAINTENA, REXULTI, Samsca/JINARC/JYNARQUE and Lonsurf—as growth drivers. We will further accelerate growth, targeting 200 billion yen in revenue, an increase of 90 billion yen, on the back of New Products scheduled to be launched during the current Medium-Term Management Plan.

Progress of 4 Global Products

The 4 Global Products made smooth progress overseas, expanding regions and adding indications. Revenue in fiscal 2019 rose 34.9% from the previous year, outperforming plan targets and making a considerable contribution to growth in consolidated performance.

ABILIFY MAINTENA

brexpiprazole | Antipsychotic long-acting injectable

As a global treatment for schizophrenia, there is increased awareness of this drug’s efficacy claims and convenient dosage formulation. Following U.S. approval in 2017 for an additional indication for the treatment of bipolar I disorder, prescriptions are increasing. In September 2019, we also filed for an additional indication for bipolar I disorder in Japan.

The global market for atypical antipsychotic long-acting injectables continues to grow as they can address the issue of medication adherence in schizophrenia and bipolar disorder. We will continue to contribute to patients around the world and aim to achieve a 30% global market share for ABILIFY MAINTENA.

REXULTI

brexpiprazole | Antipsychotic

Marketed as an adjunct treatment for major depressive disorder and as a treatment for schizophrenia in the U.S., this drug is highly evaluated for its efficacy and safety as a new treatment option for both diseases. In Japan, where the drug is marketed as a treatment for schizophrenia, prescriptions have grown significantly following the lifting of restrictions on maximum prescription period in May 2019. In Europe, sales began from April 2019.

At present, several clinical trials are under way with the aim of further contributing to treating unmet needs in the psychiatry and neurology area.

Samsca/JINARC/JYNARQUE
tolvaptan | V-receptor antagonist

Samsca is highly evaluated in various guidelines in Japan, and prescriptions are increasing for the treatment of cardiac edema and hepatic edema. Prescriptions for the treatment of the intractable disease ADPKD are increasing due to the promotion of proper use guidelines and disease awareness activities.

In May 2018, JYNARQUE was launched in the U.S. as a treatment for ADPKD. Efforts to raise disease awareness and make clinical trial data available have helped spread recognition of both the disease and the drug, resulting in a steady increase in prescriptions. In Europe also, JYNARQUE is sold in approx. 20 countries and the number of patients receiving treatment through the drug is on the increase.

Lonsurf
trifluridine/tipiracil | Anti-cancer agent

Lonsurf is growing as a treatment option for advanced colorectal cancer with the help of enhanced promotion activities. Lonsurf has also received marketing authorization for the additional indication of previously treated metastatic gastric cancer in the U.S. (February 2019), Japan (August 2019), and Europe (September 2019). Further clinical studies are currently ongoing or being planned with business partners and academia to maximize the value of Lonsurf.

Global Use as an ADPKD Treatment

Estimated number of ADPKD patients

U.S.: 140,000, Europe: 205,000, Japan: 31,000

(As of March 31, 2020, in house survey)

Initiatives to Maximize the Value of Global Products

In 2019, our North American prescription Pharmaceutical Business contributed to an impressive start of the Third Medium-Term Management Plan.

We continued to see strong revenue growth across our CNS and nephrology franchises. Established products like REXULTI, ABILIFY MAINTENA, and our newest, JYNARQUE, continued to perform well and exceeded sales forecasts. This not only speaks to the efficacy and clinical value that these products are bringing to patients and healthcare professionals, but it is also a direct result of the hard work and dedication of Otsuka people across the organization.

The whole leadership team of the North American Pharmaceutical Business is committed to maximizing the value of our entire portfolio of global products. Consciously, we seek new business opportunities to drive future growth and ensure that we continue to operate from a position of strength and innovation.
Nutraeutical Business

The Third Medium-Term Management Plan calls for revenue growth of 40 billion yen in the 3 Major Brands—POCARI SWEAT, Nature Made, and N&S—and 40 billion yen in the 3 Nurture Brands—BODYMAINTÉ, EQUI'LLE, and Daisa. Furthermore, we are working to maintain a high-profit structure capable of a sustained business profit margin of 10% or higher by creating new product concepts in anticipation of changes in business and other landscapes and by expanding into new categories and new regions.

Furthermore, given higher levels of health consciousness, we are strengthening our global sales structure to expand into new regions where we expect growth in demand for health beverages. In the future, we aim to grow POCARI SWEAT into a 100-billion-yen brand by further enhancing brand strength through original marketing that thoroughly communicates the product concept.

POCARI SWEAT

Overseas, mainly in Asia, sales volume for POCARI SWEAT, a beverage for replenishing fluids and electrolytes, is increasing due to awareness activities tailored to the characteristics and needs of each region. The CAGR of the Asia-Pacific sports beverage market was 4.9% for the period 2015 to 2019. We intend to outpace recent market growth, forecasting a CAGR of 9.4% in overseas revenue for POCARI SWEAT during the period of the Third Medium-Term Management Plan.

Sports Beverage Market (Asia-Pacific*)

Furthermore, the development of free-from products to meet evolving consumer needs.

Nutrition & Santé (N&S)

The organic food market in Europe has grown in recent years as more health-conscious consumers demand safer and more trustworthy foods. Trends such as “free-from” foods and alternative products are attracting the attention of the millennial generation. In fiscal 2019, the European meat-free food market was worth approximately 1.8 billion U.S. dollars, having grown rapidly over the past five years at a CAGR of 11.9%, while the gluten-free food market was worth around 2.5 billion U.S. dollars after expanding at a CAGR of 12.3%.4

Self-medication is increasingly prevalent in the U.S., and in recent years, related demand has continued to increase, driven by factors that include medical cost inflation. The U.S. supplement market continues to grow at a CAGR of 3.7%. We aim to turn Nature Made into a 100-billion-yen brand by developing products that incorporate cutting-edge science and by taking on challenges in new categories.

NATURE MADE

Pharmavite is a leading company in the U.S. supplement industry. Under the Nature Made supplement brand, Pharmavite develops and markets products free from flavorings, colorings and preservatives. With a lineup of high-quality supplements, key items of which have been verified as meeting the strict quality criteria set by the United States Pharmacopoeia (USP), Nature Made is the leading choice of U.S. pharmacists in nine product categories.

Third Medium-Term Management Plan

Review management assets that underpin the value chain

Business Profit Plan

Maintain at 10% or higher

New Products Global Operations New Businesses

Build a resilient business foundation

Second Medium-Term Management Plan

Review management assets that underpin the value chain

Progress of 3 Major Brands

POCARI SWEAT

3 Nurture Brands

3 Major Brands


4.9%


POCARI SWEAT overseas revenue plan

CAGR (2018–2023)

9.4%

China India Indonesia Malaysia Other

Emerging International of the U.K. (Retail Value ($) 2018

Nutraceutical Business

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Progress of 3 Nurture Brands

BODYMAÎNT

BODYMAÎNT was commercialized based on research conducted by Otsuka Pharmaceutical on the themes of “intestines and nutrition” and “exercise and nutrition.” Focusing on health management for athletes exposed to risks related to intense training, we developed BODYMAÎNT (Drink), a conditioning food that has won the support of many athletes and sports trainers. Its main ingredients include lactic acid bacteria B240, a proprietary ingredient, as well as BCAA, arginine, and whey protein. In addition, we developed BODYMAÎNT Drink, a conditioning beverage containing lactic acid bacteria B240, to help replenish fluids and electrolytes that support proper hydration. BODYMAÎNT Drink expands the value of this product line by supporting the health management of more consumers.

EÂQUELIÈ

EÂQUELIÈ originated from research conducted at Otsuka Pharmaceutical’s Saga Nutraceuticals Research Institute, where women’s health is a research theme. EÂQUELIÈ, which contains equol, is sold in Japan and the U.S. as a food product that supports women’s health and beauty at a time when aging brings physical and mental changes. In Japan, we have deployed dedicated staff with expert knowledge of women’s health nationwide. With the cooperation of physicians, pharmacists, and other healthcare professionals, we convey the importance of personal care to women who are experiencing physical and mental changes, among other activities aimed at maintaining and improving the health of women and enhancing quality of life.

DÂiya

DÂiya Foods develops, manufactures, and sells high-quality, creative plant-based food products such as cheese alternatives, yogurt alternatives, dressings, and desserts. Its brand, DÂiya, is enjoyed not only by vegetarians and people with food allergies, but also by the health-conscious millennial generation.

Social Issues Targeted by the Nutraceutical Business

Social Issues Targeted by Otsuka

1. Irregular and Unbalanced Diets

While there is seemingly an abundance of food in the developed world, diversification in daily routines and an increase in single-person households contribute to eating alone, skipped meals, and unbalanced diets. This can lead to poor physical and mental well-being. The Otsuka group is tackling various social issues related to nutrition by developing nutritional products and implementing dietary education activities.

Leveraging expertise in concentrated liquid diets from our clinical nutrition business, we created Calorie Mate, which provides nutrition for general consumers. It supports healthy dietary life in busy modern lifestyles, and is a pioneer in nutritionally balanced foods in Japan. As the top-selling brand, it continues to lead the field. Compact and with a long shelf life, Calorie Mate is convenient as a nutritional food for use during sports, when there is no time for breakfast or other meals, and during work or study, and can also be kept as a disaster provision.

2. Women’s Health

Women experience mental and physical changes throughout their lives. The effects of rapid hormonal changes are felt by women in their 40s and 50s in particular, which can impact their social life. The Otsuka group has identified women’s health as one of the priority areas of its Nutraceutical Business. We are disseminating information to promote better understanding of physical changes in women and developing related products.

Otsuka Pharmaceutical’s Saga Nutraceuticals Research Institute conducts research on total health maintenance for women in their 40s and older, including research into symptoms of menopause, bone and skin issues, and blood vessel health, and continues to generate evidence on active ingredients. In addition, our experts in women’s health carry out activities throughout Japan to spread accurate understanding of the mental and physical changes experienced by women and related health issues, as well as solutions to those issues.

3. Environmental Issues

Given that global warming is a major social issue, public attention is focused on CO2 emissions from food production as part of realizing a carbon-free society. The plant-based foods that DÂiya Foods develops, manufactures and sells have a low carbon footprint, reduce environmental load, and are more sustainable. DÂiya Foods was founded on the belief that plant-based living is better for people’s health and better for the planet. Its range of plant-based foods resonates with many people and as a category leader it is evolving into a high-growth company.

Soys are a part of Japan’s traditional food culture and contain quality dietary proteins, and have been referred to as “the meat of the fields.” Focusing on the high nutritional value and potential of soys, Otsuka Pharmaceutical has developed and commercialized soy-derived nutritional foods under three brands at its in-house research center—

SOYJOY, SOYSH+, and SoyCare. Soybeans directly consumed by people around the world account for a mere 6% of total soybean production. Beef is one source of protein, but to produce 1 kilogram of beef, it is said to take 10 kilograms of grain, such as soybeans. There is data suggesting that the production of soybeans requires one-fifth of the water and one-twentieth the amount of energy needed to produce the same volume of beef. Based on the concept of “Soyolution” (soy + solution), Otsuka Pharmaceutical provides solutions for both human health and environmental issues through a range of soy products.
Looking ahead to the Fourth Medium-Term Management Plan

Opportunities and Risks

As a total healthcare company, the Otsuka group conducts activities not only related to diagnosis and medication, but also to contributing in maintaining and improving the health of healthy people. Medical cost inflation due to aging populations and the increasing sophistication of medical treatment are a serious issue for Japan and the rest of the world, and in particular a risk to the Pharmaceutical Business. However, from the perspective of the Nutraceutical Business, we regard increased awareness of self-medication, prevention and daily health as an opportunity.

Pharmaceutical Business

- Providing total healthcare solutions, from diagnosis to treatment.
- Global R&D and marketing assets in the psychiatry and neurology area, and the cardiovascular and renal area.
- Presence in the oncology area in Japan.
- Stable profit in the intravenous solutions business.

- Advances in science and technology, progress of basic research related to diseases.
- Promotion of personalized medicine.

- Global operations in the oncology business.
- Management personnel for diversifying businesses.
- Patient explosion of market products.
- Global drug price control policies and promotion of generic drug use due to medical cost inflation.
- Intensifying competition in core areas.
- Restrictions on sales promotion activities due to stricter regulations.

Nutraceutical Business

- Creative products and marketing backed by scientific evidence.
- Ability to nurture brands.
- Overseas businesses that incorporate solutions to social issues with their core business processes.
- Steady earnings power.

- Restrictions on sales promotion activities due to stricter regulations.
- Sluggish overall beverage market due to unseasonal weather.
- Cultural differences regarding raw materials and taste preferences.

Our Approach to Issues

In recent years, Taiho Pharmaceutical, a pioneer in oral oncology products in Japan, has been actively promoting globalization, mainly by establishing its own marketing structure in the U.S. and expanding its sales networks in other regions. In addition, group companies, including Otsuka Pharmaceutical, Asics Pharmaceuticals and Taiho Pharmaceutical, are combining their assets to strengthen group-wide global operations, as well as promoting strategic alliances with external partners.

Initiatives in the Pharmaceutical Business

Psychiatry and Neurology

Aiming to become a top-class global player in the psychiatry and neurology area, with a high-potential pipeline and product portfolio

Psychiatric diseases such as schizophrenia, bipolar disorder, and major depressive disorder can develop at any age and affect a person’s social life, career, and studies. Moreover, concerns are growing about the increasing frequency of Alzheimer-related dementia as populations worldwide continue to age. These diseases affect not just the patient’s quality of life; they also place a strain on family members and caregivers, as well as on the healthcare economy. There are still many psychiatric and neurological diseases for which satisfactory treatments have yet to be established. This is because their causes and mechanisms are not fully understood, which makes the discovery of new drugs extremely difficult. The Otsuka group entered the psychiatry and neurology area in the 1970s and has continued to take on the challenge of new drug discovery with the goal of contributing to medical needs.

Agitation Associated with Dementia of the Alzheimer’s Type

It is estimated that approximately 3.4 million people* in the U.S. have Alzheimer's disease, and it is thought that a large number of those patients exhibit some form of behavioral disorder (agitation), such as excessive motor activity, and verbal or physical aggression. This kind of disorder places a burden on patients and caregivers, impacting quality of life. The Otsuka group aims to market the world’s first treatment for agitation associated with dementia of the Alzheimer’s type. Clinical trials are under way on two new drugs with different mechanisms of action, brexpiprazole (REXULTI) and AVP-786.

<table>
<thead>
<tr>
<th>Pipeline</th>
<th>Features</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPC-44005</td>
<td>Serotonin, norepinephrine and dopamine reuptake inhibitor</td>
<td>Attention deficit hyperactivity disorder</td>
<td>U.S./Europe/China</td>
<td>Phase II</td>
</tr>
<tr>
<td>OPC-214870</td>
<td>Epilepsy</td>
<td></td>
<td>Japan</td>
<td>Phase I</td>
</tr>
<tr>
<td>AVP-786</td>
<td>NMDA receptor antagonist; serotonin and norepinephrine reuptake inhibitor; sigma-1 receptor agonist</td>
<td>Negative symptoms of schizophrenia</td>
<td>U.S.</td>
<td>Phase I</td>
</tr>
<tr>
<td>centanafadine</td>
<td>Norepinephrine, dopamine and serotonin reuptake inhibitor</td>
<td>Intermittent explosive disorder</td>
<td>U.S.</td>
<td>Phase I</td>
</tr>
<tr>
<td>SAD-205</td>
<td>PDD syntheses inhibitor</td>
<td>Attention deficit hyperactivity disorder</td>
<td>U.S.</td>
<td>Phase II</td>
</tr>
<tr>
<td>fremanezumab</td>
<td>Anti-CGRP antibody</td>
<td>Migraine</td>
<td>Japan</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

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**Oncology**

Maximizing business value by combining group strengths

Taiho Pharmaceutical engages in drug discovery, leveraging its long-standing proprietary platform focused on biochemical modulation, as well as drug discovery based on its research platform, such as the newly established Cysteinomix and kinase target drug discovery. Furthermore, through its collaboration with Astex Pharmaceuticals’ fragment-based drug discovery technology, Taiho Pharmaceutical continues to discover new molecular targeting drugs.

Meanwhile, centering on external collaborations, Otsuka Pharmaceutical is taking on the challenge of establishing therapies with a focus on the future. This includes creating synergies with new modalities, in areas such as gene-modified T cell therapies and oncolytic virus therapies. Individual group companies are combining their drug discovery technologies and assets to bolster global operations and enhance business value.

**Strengths in Drug Discovery at Taiho Pharmaceutical**

As a specialty pharmaceutical company in the oncology area, Taiho Pharmaceutical is utilizing its proprietary drug discovery platforms and developing highly-effective, novel anti-cancer agents that contribute to the diversification of cancer treatment. In addition to further developing and enhancing our platform technologies for drug discovery, we are accelerating our R&D by complementing our proprietary technologies through collaborations with research organizations both in and outside Japan. Furthermore, through our corporate venture capital, we have built a proprietary network that gives us access to creative and innovative technologies and drug discovery seeds outside the company. Through research and development of promising new drugs, Taiho Pharmaceutical will contribute to a society enriched by smiles, and pursue the realization of a sustainable society.

**Strengths in Drug Discovery at Astex Pharmaceuticals**

As an established world leader in fragment-based drug discovery, Astex celebrated its 20th anniversary in 2019. In that time we have created a broad portfolio of programs in oncology and CNS and a successful track record of strategic alliances with pharmaceutical collaborators resulting in two approved anti-cancer agents within the last three years. Our innovative culture and collaborative spirit have continued to flourish as part of the Otsuka group as we have established new collaborations and further developed our technology that we hope will result in many new product approvals in the future.

**Cardiovascular and Renal System**

Creating first-in-class products through new drug discovery technologies, and medical devices

In the cardiovascular and renal area, in addition to strengthening our proprietary drug discovery platforms, we also plan to actively make growth investments, examples of which have included our business alliance with Akebia Therapeutics for vadadustat, and the acquisition of Visterra, a company with a renal-disease-related pipeline. We also strive to find solutions to unmet needs in non-pharmacological areas too. We are advancing development of unique medical devices, drawing on our innovative technology and our strengths in drugs and clinical research. Examples include a device for ultrasound renal denervation treatment and a peripheral artery stent system. We aim to create first-in-class products leveraging these new drug discovery technologies and medical devices.

<table>
<thead>
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<tr>
<td>TASI-118</td>
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<td>Gastric cancer</td>
<td>Japan</td>
<td>Phase II</td>
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<tr>
<td>guadecitabine</td>
<td>DNA-methyltransferase inhibitor</td>
<td>Acute myeloid leukemia</td>
<td>Japan, U.S.</td>
<td>Phase II</td>
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<tr>
<td>ASTX227</td>
<td>DNA-methyltransferase inhibitor</td>
<td>Myelodysplastic syndromes</td>
<td>U.S.</td>
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<tr>
<td>ASTX600</td>
<td>SARM inhibitor</td>
<td>Solid tumors, lymphomas</td>
<td>U.S.</td>
<td>Phase I</td>
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<tr>
<td>ASTX209</td>
<td>PARP inhibitor</td>
<td>Solid tumors</td>
<td>U.S.</td>
<td>Phase III</td>
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<tr>
<td>ASTX295</td>
<td>MMEZ inhibitor</td>
<td>Solid tumors</td>
<td>U.S.</td>
<td>Phase IV</td>
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<tr>
<td>OPS-11107</td>
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<td>Acute severe B-cell lymphoma</td>
<td>U.S.</td>
<td>Phase I</td>
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<tr>
<td>TASS-114</td>
<td>dual Fas/KVAP inhibitor</td>
<td>Metastatic cell lung cancer</td>
<td>Japan, U.S.</td>
<td>Phase I</td>
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<tr>
<td>TASS-115</td>
<td>multi-kinase inhibitor</td>
<td>Prostate cancer</td>
<td>Japan</td>
<td>Phase I</td>
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<tr>
<td>TASS-116</td>
<td>VEGFR inhibitor</td>
<td>Gastrintestinal stromal tumor</td>
<td>Japan</td>
<td>Phase II</td>
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<tr>
<td>TASS-117</td>
<td>—</td>
<td>Solid tumors</td>
<td>Japan</td>
<td>Phase III</td>
</tr>
<tr>
<td>TASS-119</td>
<td>—</td>
<td>Solid tumors</td>
<td>U.S., Europe</td>
<td>Phase I</td>
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<tr>
<td>TASS-120</td>
<td>JAK inhibitor</td>
<td>Gastrintestinal stromal sarcoma</td>
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<td>TASS-213</td>
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<td>Prostate cancer</td>
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<td>Phase I</td>
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<tr>
<td>TASS-278</td>
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<td>Solid tumors</td>
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<td>Phase I</td>
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<tr>
<td>WCR1087</td>
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<td>Gastrintestinal stromal tumor</td>
<td>Japan</td>
<td>Phase I</td>
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<tr>
<td>TAP202</td>
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<td>Gastrintestinal sarcoma</td>
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<td>Phase I</td>
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<tr>
<td>TIB-1301</td>
<td>—</td>
<td>Acute myeloid leukemia</td>
<td>Japan</td>
<td>Phase II</td>
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<tr>
<td>TMB-391</td>
<td>—</td>
<td>Prostate cancer</td>
<td>U.S., Europe</td>
<td>Phase I</td>
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<tr>
<td>NERI-1017</td>
<td>—</td>
<td>Prostate cancer</td>
<td>Japan</td>
<td>Phase IV</td>
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</table>

**Initiatives in the Nutraceutical Business**

Our two research institutes of the Nutraceutical Business investigate themes such as nutrition and exercise from original viewpoints that utilize expertise honed in our Pharmaceutical Business. Their goal is to develop and provide the world with creative products that maintain and improve people’s health and are backed by scientific evidence.

**Saga Nutraceuticals Research Institute**

Since its establishment in 1984 as Japan’s first private research institute for clinical exercise and nutrition, the Saga Nutraceuticals Research Institute has conducted R&D in various fields related to exercise and nutrition, women’s health, and other health issues. In 2014, one of the largest controlled-environment rooms in Japan was completed at the institute, enabling the recreation of hypoxic environments equivalent to those found at up to an altitude of 5,000 meters, which were previously difficult to recreate, as well as high-temperature/high-humidity and low-temperature/low-humidity conditions. This facility helps advance research into sports nutrition, such as by verifying the effects of fluid and nutritional intake in such environments.

**Otsu Nutraceuticals Research Institute**

The Otsu Nutraceuticals Research Institute was established in 2000 to advance research on intestinal immunity, with a particular focus on the intestines, which play a key role in overall health. One example of the institute’s research is related to enhancing the body’s biological barrier by increasing the secretion of immunoglobulin A (IgA), an antibody that plays a crucial role in mucosal immunity. Exploratory R&D demonstrated that lactic acid bacteria B240 heightens the function of mucosal immunity and lowers the probability of catching the common cold.

**Pipe2line**

<table>
<thead>
<tr>
<th>Pipeline</th>
<th>Features</th>
<th>Indication</th>
<th>Country/Region</th>
<th>Development Status</th>
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</thead>
<tbody>
<tr>
<td>tolvaptan</td>
<td>V2-receptor antagonist</td>
<td>Syndrome of inappropriate antidiuretic hormone secretion</td>
<td>Japan</td>
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<td>OPC-61815</td>
<td>V2-receptor antagonist</td>
<td>Cardiac edema</td>
<td>Japan</td>
<td>Phase II</td>
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<tr>
<td>vadadustat</td>
<td>HIF-prolyl hydroxylase inhibitor</td>
<td>Renal anemia</td>
<td>U.S., Europe</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

Project that has advanced in or after fiscal 2019

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Beyond 2030

Envisaging a variety of changes, including an increase in aging populations, rapid climate change, and advances in precision medicine* associated with the spread of preventive medicine and genetic testing, the Otsuka group aims to be an indispensable provider of products and services that meet the healthcare needs of the times.

* Therapeutic approaches that achieve greater precision by applying detailed genetic and other information about each patient

Pharmaceutical Business

Driven by the corporate philosophy “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 drug discovery research through multiple approaches. We will strengthen our proprietary drug discovery platform to be capable of generating new strengths and innovation. This will include utilizing the fragment-based drug discovery technology of Astex Pharmaceuticals, the unique antibody manufacturing platform technology from Visterra, and the cysteinomix drug discovery platform of Taiho Pharmaceutical, as well as building a network with and providing research support to academia and bio-ventures that possess advanced research technologies and drug discovery seeds.

Initiatives for Innovation in Research and Development Areas

- Generate innovation through collaboration and integration of proprietary R&D platforms and technologies in core areas
- Generate results from innovation seeds through various collaborations

Nutraceutical Business

Awareness of health issues is rising, including issues related to aging populations, medical costs, and the spread of infectious diseases. Our goal in the Nutraceutical Business is to support the maintenance and improvement of people’s health worldwide, and thereby contribute to longer healthy life expectancy. To this end, we will utilize the expertise we have cultivated in the Pharmaceutical Business while proposing solutions based on new concepts that address yet-to-emerge needs and social issues. With an eye on changes in the global landscape, we will take on the challenge of creating new value and expanding into new categories and regions by combining cutting-edge scientific and technological developments with our unique business model. Going forward, we will respond to various health-related social issues by continuing to implement health awareness activities that bring those issues to the forefront and offering solutions from each brand. Furthermore, we will promote these activities by strengthening collaborations with external institutions.

Otsuka Group’s CSR (Corporate Social Responsibility)

—Toward Realizing a Sustainable Society—

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

Contribution to a Sustainable Society

Otsuka’s business activities = Solving social issues = CSR

Healthier Society (Society)
Health, People, Quality in All We Do

Healthier Planet (Environment)
Climate Change, Resource Recycling and Conservation, Water Conservation

Governance
Corporate Governance, Compliance, Risk Management
The Otsuka Group’s Approach to CSR

Toward Realizing a Sustainable Society

Examples of Our Activities

- Promotion of R&D for unmet needs
- R&D of antibiotics and improvement of drug access
- Promotion of healthcare activities for people’s health maintenance and improvement mainly on exercise and nutrition etc.
- Promotion of problem solving by strengthening partnerships
- Deepening communication with stakeholders
- Promotion of “Customer-centric management”
- Activities to explain the importance of hydration
- Otsuka Health Comic Library
- Dietary education app SketchCook
- SATU HAT (“One Heart”) programs

* To give back to the local community in Indonesia, POCAE (3M471) has launched the “Making of Traders” campaign ("One Heart for Health")

SATU HAT Sehatkan Bangsa
SATU HAT Cerdaskan Bangsa
SATU HAT Peduli Lingkungan
SATU HAT Peduli Pendidikan

Basic CSR
- Human resource development
- Health management
- Strengthening corporate governance
- Risk identification, evaluation and management
- Reduce CO2 emissions throughout the value chain
- Reduce environmental impact by improving resource efficiency
- Promotion of business activities aimed at a sustainable state in both society and the earth
- Understanding water resource risk
- Management and effective use of water resources

Proactive CSR
- Risk identification, evaluation and management
- Thorough compliance
- Strengthening corporate governance
- Health management
- Diversity promotion
- Promotion of R&D for unmet needs
- R&D of antibiotics and improvement of drug access
- Support and awareness activities for people’s health maintenance and improvement mainly on exercise and nutrition etc.
- Promotion of problem solving by strengthening partnerships

Defining CSR
- Human resource development
- Diversity promotion
- Health management
- Strengthening corporate governance
- Risk identification, evaluation and management
- Management and effective use of water resources

Materiality

In 2019, the Otsuka group determined material issues based on their importance to society and to the group’s businesses. These material issues were determined to be: Society (Health, People, Quality in All We Do), Environment (Climate Change, Resource Recycling and Conservation, Water Conservation), and Governance.

<table>
<thead>
<tr>
<th>Materiality</th>
<th>Social Issues</th>
<th>Our Goals</th>
<th>Our Activities</th>
<th>Related SDGs</th>
</tr>
</thead>
</table>
| Health      | - Uremic medical and health needs
- Spread of infectious diseases
- Nutritional needs
- Increasing aging issues
- Contribute to unmet needs solutions
- Eradication of tuberculosis
- Creation of a system for the realization of a healthy life
- Healthy life extension
| - Promotion of R&D for unmet needs
- R&D of antibiotics and improvement of drug access
- Support and awareness activities for people’s health maintenance and improvement mainly on exercise and nutrition etc.
- Promotion of problem solving by strengthening partnerships |
| Society (Healthier Society) | - Prevention
- Unprepared for diversification
- Creation of a corporate culture that stimulates creativity
- Enhance employee engagement
- Human resource development
- Diversity promotion
- Health management |
| People      | - Consumption and production that impacts sustainability
- Gaining stakeholder trust
- Pursuing sustainability at all levels of the value chain
- Enhancing and establishing a quality assurance system for safety and security
- Sustainable procurement and product design
- Thorough quality control and stable supply
- Responsible promotional activities and information provision
- Deepening communication with stakeholders
- Promotion of “Customer-centric management” |
| Quality in All We Do | - Global warming
- FY 2030 Goal: 30% reduction in CO2 emissions compared to FY 2017
- Reduce CO2 emissions throughout the value chain
- FY 2030 Goal: 50% reduction in simple incineration and landfill compared to FY 2019
- FY 2030 Goal: 50% or higher content of recycled and plant-based materials in our PET bottles
- Reduce environmental impact by improving resource efficiency
- Promotion of business activities aimed at a sustainable state in both society and the earth |
| Environment (Healthier Planet) | - Environmental load increase
- FY 2030 Goal: 50% reduction in CO2 emissions compared to FY 2017
- Reduce environmental impact by improving resource efficiency
- Promotion of business activities aimed at a sustainable state in both society and the earth |
| Resource Recycling and Conservation | - Reducing freshwater availability
- FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017
- Understanding water resources risk
- Management and effective use of water resources |
| Water Conservation | - Reducing freshwater availability
- FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2017
- Understanding water resources risk
- Management and effective use of water resources |
| Governance | - Fragile governance system
- Social change risk
- Long-term improvement of corporate value
- Strengthening corporate governance
- Thorough compliance
- Risk identification, evaluation and management |

Based on our belief that CSR is integrated into our businesses across the Otsuka group, we aim to contribute to the realization of a sustainable society by solving social issues through our businesses. Therefore, we are focusing on “CSR connected with business activities” in pursuing sustainable growth and the realization of a healthy and sustainable society, or in other words, the creation of social value, including financial value and ESG aspects.

Also, we recognize that “CSR through social contribution” (which includes donation activities) and “basic CSR” (which includes governance and risk management as the foundation of our business) are indispensable parts of corporate social responsibility. We define CSR broadly as responsible efforts of our business) are indispensable parts of corporate social responsibility.

Support for the United Nations Global Compact

Otsuka Holdings became a signatory to the United Nations Global Compact (UNGCC) in 2016. While supporting the UNGC’s 10 principles, we also consider the UN’s Sustainable Development Goals (SDGs) in contributing to the realization of a sustainable society through our business activities.
Health

Under its corporate philosophy “Otsuka-people creating new products for better health worldwide,” the Otsuka group actively implements CSR initiatives based on the recognition that CSR is an integral part of our business. The desire to be healthy is universal. Every day, the Otsuka group carries out activities to prevent and treat diseases and to contribute to the maintenance and improvement of people’s health worldwide. The world continues to face a host of healthcare issues, such as the spread of infectious diseases, inadequate medical care facilities, and lack of effective therapies. In aiming to solve these issues, we constantly ask ourselves: Is it something that only Otsuka can do, and work to find solutions for unmet medical needs that the majority of other companies have yet to address. Moreover, issues such as medical cost inflation mean that maintaining and improving health is now an issue that society as a whole, not just individuals, must face head on. In addition to initiatives that raise awareness of health among individuals, the Otsuka group undertakes initiatives for maintaining and improving health in society at large, including through collaboration with local communities.

Pharmaceutical Business

The Challenge of Addressing Unmet Medical Needs

1. Psychiatry and Neurology

Japan’s Ministry of Health, Labour and Welfare has defined psychiatric disorders as one of the five major disease areas. The rising number of patients with such disorders poses a pressing global issue. However, while the list of psychiatric and neurological diseases is long, including schizophrenia, depression, bipolar disorder, and Alzheimer’s-related dementia, R&D in this area is challenging. The underlying causes of these diseases have yet to be precisely elucidated, and satisfaction with current treatment methods is low. However, patients and their families are in immediate need of new therapies. Psychiatry and neurology is a key focus area in which the Otsuka group has been making headway, namely with the development of antipsychotic drugs ABILIFY MAINTENA and REKULTI, as well as Selinco, a drug that helps in the reduction of alcohol consumption in patients with alcohol dependency. We are also taking on the challenge of developing therapeutic drugs for diseases with no effective medicines.

2. Oncology

As medical science advances, year by year progress is being made in the diagnosis and treatment of cancer. Nevertheless, there are still many diseases for which effective treatments have yet to be found, cancer remaining to be one of the leading causes of death. The oncology area, where there are still many unmet needs, is another of the Otsuka group’s key focus areas. This stems from our work since the 1970s as a pioneer in developing oral anti-cancer agents, which at that time were not widely used anywhere in the world. In addition to conventional chemotherapy and molecular targeting drugs used to treat specific organs, we are taking on challenges in the new fields of gene therapy and cell therapy in order to keep pace with the shift toward genomic medicine and personalized medicine tailored to the characteristics of the cancer in each individual patient. Going forward, we will continue to advance our R&D to deliver innovative therapeutic drugs to patients with greater speed.

3. Infectious Diseases

Tuberculosis is one of the world’s three major infectious diseases, the others being AIDS and malaria. It is the single infectious disease that accounts for the largest number of deaths. Multidrug-resistant tuberculosis is difficult to treat because it is resistant to a number of existing therapeutic drugs, and poses a serious public health hazard. Otsuka’s long period of research and development into a tuberculosis treatment culminated in the 2014 approval of tuberculosis drug DELTYBA. We are expanding access and bringing DELTYBA to more patients by obtaining regulatory approval in each country/region, and through programs developed by governments and international organizations, the Global Drug Facility launched by the Stop TB Partnership and by working with alliance partners. As of December 2019, DELTYBA is available in more than 100 countries/regions. Furthermore, we are responding to unmet medical needs by expanding indications for pediatric care and cooperating in a U.S. NIH-led prevention trial for multidrug-resistant tuberculosis. Given this need, we are advancing R&D for OPC-167832, a new therapeutic drug to follow DELTYBA.

Partnerships

1. Eradicating tuberculosis

The Global Health Innovative Technology Fund (GHIT Fund) is a public interest incorporated association and international public-private partnership involving the Japanese government, private corporations, the Bill & Melinda Gates Foundation, the Welcome Trust, and the United Nations Development Program (UNDP). It funds drug, vaccine, diagnostic and other R&D in order to leverage Japan’s high level of technology and innovation in the fight against the world’s three major infectious diseases and neglected tropical diseases, which mainly affect developing countries. Since June 2016, Otsuka Pharmaceutical has contributed to the GHIT Fund as an associate partner.

Also, in line with the goal of eradicating tuberculosis, we have participated in the planning of the Project to Accelerate New Treatments for Tuberculosis (PA-TB collaboration) since February 2020. This world-first global cross-industry collaboration between charitable and non-profit organizations and the drug industry aims to satisfy the Target Regimen Profiles (TRP) proposed by the World Health Organization (WHO) for tuberculosis by speeding up the development of a new pan-TB regimen suitable for all tuberculosis patients.

2. Initiatives in Kidney Disease

Autoimmune poly cicytic kidney disease (ADPKD) is a hereditary, intractable orphan disease. It involves the progressive development and enlargement of a large number of fluid-filled cysts in both kidneys due to genetic mutations. The kidneys grow to many times their original size, resulting in the gradual deterioration of kidney function. Otsuka Pharmaceutical has signed a comprehensive partnership agreement on ADPKD with the Japan Kidney Association, and is working to raise awareness about ADPKD and improve the level of medical care. Otsuka Pharmaceutical has signed a collaborative agreement—with the Japan Kidney Association—aimed at the practical application of basic research by young researchers in the kidney field. We are openly soliciting drug discovery research themes from academia through the Kidney Research Initiative-Japan (KRI-J)—a platform for collaboration between academia, industry and government established by the Japan Kidney Association. The signing of joint research agreements between the research institutions and Otsuka Pharmaceutical will enable us to carry out research on the selected themes.

Supplying Pharmaceuticals to More Patients

1. Fair Pricing and Improved Healthcare Infrastructure

With the aim of contributing to improved access to pharmaceuticals, the Otsuka group researches, develops and extends therapeutic drugs and N solutions that address unmet medical needs. We also work to provide pharmaceuticals at fair prices to support improved healthcare infrastructure.

One example is Otsuka Pharmaceutical Factory’s approach to N solutions, which are defined as basic drugs (a drug with high clinical necessity whose manufacturing and sales will continue to be required without interruption). * Group companies manufacture N solutions locally, which contributes to local communities, such as through the supply of products at fair prices and the creation of employment opportunities.

2. Expanding Access to Medicine

There are patients who cannot expect satisfactory outcomes from existing treatments, and also are not eligible to participate in clinical trials with critical, life-threatening diseases. Such patients are unable to access investigational drugs that might be a potential treatment option. Through its Expanded Access Program, Otsuka group provides patients that are eligible to participate in clinical trials with access to investigational drugs based on application by their physician and if they meet pre-specified conditions.

Nutraceutical Business

Initiatives for Yet-To-Be-Imagined Needs

To be healthy is a desire of people worldwide. Advances in medical technology and improvements in public health have extended life expectancy globally, but have also given rise to new health issues. The Otsuka group’s Nutraceutical Business is centered on functional beverages and functional foods that support the maintenance and improvement of day-to-day health. Our activities enable people worldwide to live healthy and independent lifestyles. Our contribution to health is not only helping to treat diseases, but also helping healthy people stay healthy through nutrition.

Current social issues include extending healthy life expectancy, responding to decreasing birthrates and aging populations, and controlling medical costs. We have set “the essence of life” as a theme for contributing to health. Under this theme, we are engaged in product development and information provision activities that are backed by scientific evidence based on applied expertise from the Pharmaceutical Business.

1. Health Maintenance and Improvement Initiatives in Coordination with All 47 Prefectures of Japan

The Otsuka group is promoting community-based health maintenance and improvement initiatives, as well as disaster prevention and relief activities. As an example, Otsuka Pharmaceutical has concluded health-related partnership agreements with all 47 prefectures of Japan. We are cooperating with local governments to find solutions to the health issues of people living in each region, which includes applying our knowledge and expertise on topics such as dietary education, preventive lifestyle diseases, prevention of heat disorders, sports promotion, women’s health and disaster countermeasures.
explain the importance of nutrition, based on expertise obtained during the R&D process, we conduct dietary education activities to spread accurate understanding of the mental and physical changes experienced by women and related health issues. The effects of rapid hormonal changes are felt by women in their 40s and 50s in particular, which can be difficult to acquire.

For busy modern adults, we provide, in Japan, our app SketchCook helps teach proper dietary habits and nutrition of a child in which such information can be difficult to acquire.

While greater participation in the workforce, women are faced with the issues of balancing work with childcare, nursing care, and personal health. The effects of rapid hormonal changes are felt by women in their 40s and 50s in particular, which can impact their everyday work and private lives. Therefore, creating a healthy lifestyle is a central issue under the Health Japan 21 (the second term) plan established by the Ministry of Health, Labour and Welfare.

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3. Raising Awareness of Women’s Health

The Japanese average life expectancy is over 80 years for both men and women. However, in terms of how healthy life expectancy is defined as the period in which a person can live without being bedridden and without limitation to daily activities due to health issues. The difference between the average life expectancy and healthy life expectancy is about 9 years for men and 12 years for women in Japan. Therefore, extending healthy life expectancy is a priority nationwide.

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We began publishing the Otsuka Health Comic Library in 1989 to promote sound growth and development of health habits among children of the next generation. Produced with editorial supervision from the Japan Medical Association and the Japan Society of School Health, and endorsed by the Japanese Pediatric Society, the library seeks to convey basic health knowledge to children, covering topics such as the makeup of the human body and nutrition, in a broad, easy-to-understand manner through medium of comics. Every year we choose a different theme and publish a new volume. The comics are donated by elementary schools, special needs schools, Japanese schools overseas, and public libraries.

Each year’s theme is decided based on requests from schools and the opinions of organizations involved in school health. With the cooperation of experts in various fields, we are finding ways to deliver factual, accurate health information to children in a fun way. We are also working to make the comics a more useful part of school health education. Since 2015, together with the Japan Society of School Health, we have sponsored a lecture by health experts and usage demonstrations of the library at schools. We are continuing to evolve 30 years after the first volume, and deepening our ability to communicate the value of health.

2. Disaster Relief and Other Support

In light of our obligation as a company that handles items for medical use. Overseas, we donated group products such as IV solutions, therapeutic drugs, foods and beverages, we actively engage in disaster relief activities and disaster victim assistance.

Our support for measures to counteract COVID-19 is one such example. In Japan, we supplied products such as beverages as well as masks and protective clothing for medical use. Overseas, we have been donating group products such as beverages and medical products to local healthcare facilities and chapters of the Red Cross Society, in addition to making monetary donations to such organizations.

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Basic Policy
The Otsuka group actively promotes diversity based on the belief that active participation by a wide range of employees further advances innovation and globalization. Accordingly, as a corporate group constantly in pursuit of innovation, we are endeavoring to establish a richly diverse workplace environment.

Approach
Since the 1980s, a time when the concept of diversity had yet to gain wide acceptance, our top management had actively promoted diversity in the belief that active contributions from personnel with diverse nationalities, races, ages, genders, disabilities, sexual orientations and other characteristics are essential in creating innovative products and ideas that drive corporate growth.

The Otsuka group has stated its commitment to promoting diversity in the Otsuka Group Global Code of Business Ethics. Furthermore, in 2017 the group became a signatory to the Women’s Empowerment Principles (WEPs), a set of corporate principles primarily developed by the United Nations Global Compact (UNGC) and UN Women1 that offers guidance on how to empower women in the workplace.

To demonstrate our commitment as a signatory to the WEPs, we have introduced a number of systems that meet WEPs at group companies in Japan. Notable examples are the Work Interval System, which mandates minimum rest periods for workers, and the Family Smile Support System, which encourages employees to work from home if necessary to deal with childbirth, childcare, caregiving, and nursing care, thus achieving better work efficiency, productivity, and work-life balance. We also regularly hold group-wide training on women’s empowerment. In order to support our diverse employees in pursuing career continuity, we have enhanced childcare, nursing care, and other systems at each group company and have opened daycare centers at three of our business premises (in Tokushima, Osaka, and Tsukuba) to help employees balance childcare and work.

Moreover, we are actively conducting diversity promotion initiatives such as group-wide seminars with the theme of LGBT, with the aim of achieving a more inclusive workplace. As a company developing and supplying anti-cancer agents, Taisho Pharmaceutical has a team to realize “Workplace support for employees with cancer.” This team, mainly composed of the Human Resources Department and occupational nursing staff, aims to create a workplace where employees with cancer or other diseases can receive treatment while continuing to work. Taisho Pharmaceutical has been recognized with an Excellence Award from the Tokyo Metropolitan Government for its outstanding initiatives under this support framework that helps cancer patients balance treatment and work.

Furthermore, Otsuka Pharmaceutical established Heartful Kawauchi in Tokushima City in 2011 as a special purpose subsidiary. This subsidiary enables people with disabilities to fully realize their potential.

2. United Nations Entity for Gender Equality and the Empowerment of Women
3. Board network system for increased flexibility

External Recognition

Naideko Brand
System for selecting companies that actively promote the employment and advancement of women.
(Ministry of Economy, Trade and Industry, Women’s Empowerment: Tokyo Stock Exchange) Selected in 2020: Otsuka Holdings*

Platinum Kurumin and Kurumin
Certification system 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 effective measures to empower women in the workplace (Ministry of Health, Labour and Welfare)

Kurumin: Otsuka Pharmaceutical
Platinum Kurumin: Otsuka Pharmaceutical, Taisho Pharmaceutical
Kurumin: Otsuka Pharmaceutical, and others

Eruboshi
Certification system based on the Act on Promotion of Women’s Participation and Advancement in the Workplace. Companies are recognized for excellent efforts to empower women in the workplace (Ministry of Health, Labour and Welfare)

Eruboshi (highest grade): Otsuka Chemical

Diversity Management Selection 100
System recognizing companies that have improved corporate value through diversity management. (Ministry of Economy, Trade and Industry) 2014 Award: Otsuka Pharmaceutical

Health & Safety
Programme
Participants in Health Seminars held by the group for employees and family members: 1,050 (Cumulative)
Participants in Anzen Dojo programs (Otsuka Pharmaceutical): 658 (Fiscal 2019)

Basic Policy
The Otsuka group recognizes that the mental and physical well-being of each and every employee is indispensable to realizing the group’s shared corporate philosophy. To this end, we are committed to creating a safe workplace environment and are continuously implementing initiatives to help employees maintain and improve their health.

Approach
The major Otsuka group companies have issued a declaration on health under which they strive to create a workplace environment conducive to employee health maintenance and improvement. As part of efforts led by Otsuka Holdings, officers in charge of health management at each group company cooperate with the Otsuka Pharmaceutical Health Insurance Association and medical professionals in activities aimed at improving the health of employees. One such activity is the hosting of Health Seminars for group employees and their families. Held in major cities across Japan, these seminars are aimed at communicating the group’s initiatives on health, introducing the Otsuka Pharmaceutical Health Insurance Association, and disseminating information relevant to improving the health of employees and their families. Another activity is the group-wide Tokushima Health Project, known as TOKI-L, launched in 2017 under the theme of creating lively and cheerful workplaces by lowering the risk of lifestyle diseases. This project targets the Tokushima region—where the greatest concentration of group employees live and work—and focuses on raising awareness of health issues in the region as a whole. The project promotes walking, exercise and a healthy diet.

Improving Workplace Health and Safety
For the purpose of creating a safe and secure workplace, at factories and other business sites of each group company in Japan we have established safety and health committees, as defined in the Industrial Safety and Health Act. We actively carry out workplace health and safety inspections, as well as the regular revision and improvement of workplace health and safety management systems.

In addition, the Otsuka group is working to ensure appropriate management of health and safety through the joint meetings of health and safety management officers at each group company, sharing information on relevant education and training. These activities are reported at health and safety committee meetings and form the basis for improvements to the workplace environment. Furthermore, major group companies hold a joint meeting every year to share reports on workplace accidents and recurrence prevention measures.

Otsuka Pharmaceutical, which handles chemical substances, conducts various workplace safety initiatives. Major initiatives include a system for swift information sharing on issues related to factory operations among all domestic and overseas locations, as well as regular reporting of group safety at Board of Directors meetings. Another key initiative is Anzen Dojo, an experience-based safety training center which opened in 2012 as part of measures to prevent occupational accidents. The center runs training programs aimed at improving safety awareness for group employees, employees of overseas affiliates, and third parties. Through classroom instruction and simulations of past accidents, the center reinforces lessons from failures and safety knowledge, sharpens awareness of danger, and develops the ability to identify potential risks. In recognition of its activities to improve health and safety education and establish a safety culture through Anzen Dojo, Otsuka Pharmaceutical received an RC Outstanding Award from the Japan Chemical Industry Association at the 8th Annual Responsible Care Awards in 2014.

External Recognition

Nadeshiko Brand
System for selecting companies that actively promote the employment and advancement of women.
(Ministry of Economy, Trade and Industry, Women’s Empowerment: Tokyo Stock Exchange) Selected in 2020: Otsuka Holdings*

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Eruboshi (highest grade): Otsuka Chemical

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System recognizing companies that have improved corporate value through diversity management. (Ministry of Economy, Trade and Industry) 2014 Award: Otsuka Pharmaceutical

Health & Productivity Management Outstanding Organization* (White 500) (large enterprise category)

Otsuka Holdings, Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory

Health & Productivity Management Outstanding Organization* (large enterprise category)

Taisho Pharmaceutical, Otsuka Techno

Health & Productivity Management Outstanding Organization* (SME category)

Otsuka Electronics, JIMRO, Otsuka Wellness

* The Health & Productivity Management Outstanding Organization Recognition Program recognizes organizations working to overcome health-related challenges in local communities or to promote health-conscious activities led by the Japanese Kiroko Kogo, and recognizes organizations for outstanding efforts in health and productivity management.
Quality in All We Do

To help build a sustainable society, the Otsuka group seeks to achieve sustainability by addressing environmental and social issues and by establishing a quality assurance structure that ensures safety and reliability at every stage of the value chain.

R&D

1. Ethical Considerations Concerning Appropriate R&D

The use of experimental animals to verify efficacy and safety in R&D is at times necessary. The Otsuka group complies with all related laws, ordinances, and guidelines while striving to uphold scientifically valid methodologies and ethical considerations from the viewpoints of animal protection and welfare, including the lives of the animals; preservation of the environment; and the safety of experimenters.

As an in-house management system, we have developed and implemented rules on experiments that involve animals, have established an Animal Experiment Committee, and properly carry out animal experiments and breeding. The Animal Experiment Committee evaluates whether each proposed animal experiment plan is appropriate based on the 3Rs principles. These are Replacement/avoidance or replacement of animal use, Reduction/Minimization in the number of animals used, and Refinement/Minimization of animal suffering. Based on these, we conduct researcher education and internal inspections and evaluations of the implementation of experiments involving animals.

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

Procurement

Basic Policy

The Otsuka group, together with its business partners, aims to contribute to building a sustainable society by promoting CSR procurement that takes into consideration factors such as legal and regulatory compliance, the environment, and the protection of human rights.

Approach

Across the entire value chain, the Otsuka group engages in business activities that are safe, reliable, socially acceptable, and in compliance with laws and regulations. When commencing transactions with a supplier, 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 the case of a new supplier, transactions are determined only after we have carried out due diligence. In the case of a new supplier, transactions are determined only after we have carried out due diligence. We also conclude a basic transaction agreement.

Partners surveyed through the self-assessment questionnaire: 34 (Cumulative)

1. Collaboration with Business Partners

We conduct surveys of business partners using the CSR procurement self-assessment questionnaire* published by UN Global Compact Network Japan. In 2018, we asked 26 companies to complete the survey, and received responses from 25. In 2019, nine companies were selected, all of whom responded.

We assess our business partners not only with respect to legal and regulatory compliance but also with respect to their activities regarding human rights, labor, the environment, and anti-corruption measures. The results of the survey are provided to partners as feedback to further promote CSR procurement.

Guidelines to provide more specific descriptions of the provisions of the above vision and policy. In order to ensure a stable supply of products, we perform advance risk assessments on key raw materials to identify potential risks so that we can take countermeasures. We also make sure to source raw materials from multiple companies, in principle. For products that use palm oil, for example, Otsuka Pharmaceutical confirms that its business partners are RSPO* members before purchasing raw materials.

* Roundtable on Sustainable Palm Oil

1. Production

Production departments at the Otsuka group employ a traceability system covering all stages of the value chain, from raw material procurement to production, distribution, and sales, thereby enabling thorough management throughout the entire value chain.

Moreover, for over 30 years, production departments have held a global production meeting aimed at group-wide improvements by sharing techniques and information.

2. Quality Control Activities for the Pharmaceutical Business

Basic Policy

The Otsuka group always puts its customers first. To this end, it has built and maintains safety control and operation systems that take into account the characteristics of each of its businesses, which include pharmaceuticals, foods and beverages, chemicals, and cosmetics. Proper assurance of quality is the foundation for the efficacy and safety that enable pharmaceutical products to be used in medical care.

In addition, while complying with the laws and regulations in each country, for example the Pharmaceutical and Medical Devices Act in Japan, we engage in quality control and post-marketing surveillance to ensure safety in accordance with GDP and GVP standards. We also make reports, as well as compile and revise various documentation, for submission to the relevant regulatory authorities. We have also established a system for constant global pharmacovigilance that collects and assesses product safety information, including on side effects.

We continue to promote the results of our monitoring to medical institutions and other relevant parties.

* GDP: Good Distribution Practice

1. GQP: Good Quality Practice

2. GVP: Good Voltage Practice

2. Joint Business Partner Audit by Pharmaceutical Companies

In the Otsuka group, four pharmaceutical companies conduct joint business partner audits for shared suppliers of raw materials. We began these audits in 2016, applying proprietary methodologies and including an auditor skills training program.

3. Global Product Quality Team Activities for the Pharmaceutical Business

Since 2016, Otsuka Pharmaceutical and its group companies have conducted activities to enhance compliance with GDPs* for a range of processes from development through to the finished product. Among initiatives to improve quality control systems, we hold annual meetings attended by management personnel, as well as group-wide meetings.

The Pharmaceutical Business established global product quality policies in 2017. Activities are carried out globally, and include ensuring the reliability of quality data and compiling procedural manuals.

* GDP = Good Distribution Practice

2. Quality Control and Patient/Customer Safety

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* GDP = Good Distribution Practice

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3. Quality Control Activities for the Nutraceutical Business

In 2018, Otsuka Pharmaceutical established the Quality Division for the purpose of further facilitating quality improvement and safety control for products in the Nutraceutical Business. Furthermore, with the establishment of the Quality Assurance Office, we have implemented a system based on GMP for pharmaceuticals. The system enables central management of all processes from identifying and verifying risks arising from changes, to investigating causes and taking remedial action when risks manifest. As of May 2020, all of our factories in Japan that manufacture nutraceuticals are certified for the FSSC 22000 food safety standard.
5. Collaboration between Pharmaceutical and Nutraceutical Departments

Product quality departments of the Pharmaceutical Business and Nutraceutical Business jointly hold an annual global product quality management meeting. The 2019 meeting was attended by around 100 managers and quality supervisors for pharmaceuticals and nutraceuticals from 22 companies in nine countries.

The meeting is an opportunity for participants to review the preceding year’s quality control performance and to work on improving quality control and developing personnel by sharing reports that illustrate the need for predictive risk management in production activities, based on the importance of learning from examples of issues as well as successes.

Logistics

Basic Policy

The Otsuka group handles products that relate directly to human life, including pharmaceuticals, foods, and beverages. As such, we ensure the rigorous control and maintenance of product quality throughout distribution, and actively take measures to ensure stable supply in the event of a natural disaster or other emergency situation. The group also promotes environmentally friendly logistics operations through measures such as reducing CO₂ emissions.

Approach

The Otsuka group delivers products throughout Japan, mainly via group company Otsuka Warehouse. Otsuka Warehouse has set up the GDP* Promotion Office to facilitate appropriate logistics in accordance with the GDP guidelines for pharmaceuticals. We disseminate the principles of the GDP guidelines among personnel engaged in the manufacture and distribution of pharmaceuticals through training and drills on quality management systems, document control, administration of outsourced processes, facility and equipment maintenance, storage and transport operations, assessment of supplier and customer eligibility, among others. In addition, we conduct regular training to ensure compliance with internal standards and procedures.

We also strive to standardize data management system specifications in order to facilitate collaboration and cooperation between shippers and logistics operators.

Specifically, we are improving logistics quality by introducing IT systems for truck dispatch and vehicle monitoring, which enable better tracking of transport and delivery status.

Other initiatives include computerizing warehouse operations to reduce incorrect shipments and mispick, thereby helping quality improvement through higher efficiency. The diverse assortment of shipping forms has been standardized and digitalized, with benefits that include lower mishandling rates when orders are changed.

Otsuka Warehouse is working to ensure stable supply by establishing distributed storage facilities across Japan to maintain adequate product stocks that reflect product characteristics. Furthermore, for pharmaceuticals, a framework for business continuity planning (BCP) has been established that ensures essential products can be delivered to those who need them. In addition to securing stock, measures include developing an emergency response system for transporting products, for example registering vehicles for authorized access to restricted areas and exchanging MOUs with shippers, warehouse owners and other partners for cooperation in the transport of emergency relief supplies.

Sales and Marketing

Basic Policy

The Otsuka group believes that it has a responsibility to deliver high-value products and services to customers. To do so, we will engage in suitable promotion and advertising activities that comply with laws and regulations, and communicate with customers in an appropriate manner.

Approach

The Otsuka group has expanded on the JPMA Promotion Code for Prescription Drugs—a code of behavior for healthcare professionals issued by the Japan Pharmaceutical Manufacturers Association (JPMA)—to formulate its own Code of Practice aimed to disperse information about products, related knowledge and the latest academic information in order to provide appropriate information to healthcare professionals. Issued by the Scientific Affairs Department, the Code for Prescription Drugs—a code of behavior for healthcare professionals—ensures that Otsuka products are suitable for the consumer market due to being short-dated, in poor condition external packaging or other reasons. From 2019, to further reduce food loss, we began selling these products to group employees. These initiatives helped us eliminate approximately 131 tons of food loss in 2019.

Other initiatives include

2. Reducing Food Loss

The Otsuka group seeks to address food loss issues by producing foods and beverages with longer shelf lives and with expiration dates that are indicated by the month rather than day. Some products are unsuitable for the consumer market due to being short-dated, in poor condition external packaging or other reasons. From 2019, to further reduce food loss, we began selling these products to group employees. These initiatives helped us eliminate approximately 131 tons of food loss in 2019.

Promotion of Customer-centric Management

Basic Policy

In October 2018, the Otsuka group announced its Declaration of Customer-centric Commitment, as a way of putting the corporate philosophy into practice. Promotion of customer-centric management has been targeted in activities for material issues. In conducting business, we recognize that respecting consumer rights is an important human rights issue. Our Declaration of Customer-centric Commitment establishes basic policies stating our commitment to our social responsibilities as a corporation, which we fulfill by pursuing customer-centric management and making appropriate decisions that are based on dialogue with all stakeholders.

1. Inculcating a Customer-centric Mindset in Employees

Customer-facing employees from group companies in Japan meet twice yearly to share best practices for customer service and product improvements. This helps foster a customer-centric corporate culture.

2. Enhancing Information Exchange with Customers and Mechanisms for Reflecting Customer Feedback

Each group company establishes dedicated customer contact points for patients, healthcare professionals and general consumers, and provides appropriate training for the employees who work there. For example, the assignment of specially trained female operators enables us to better answer inquiries about products designed for women. This approach helps us deepen communication with customers, provide appropriate information and reflect customer requests and suggestions in product improvements.

One such product improvement was for OS-1 Jelly* and OS-1 Jelly**, produced by Otsuka Pharmaceutical Factory. These products are foods for persons with medical conditions. We have redesigned allergen labelling by adding a list of allergens (mandatory and recommended items), and a clear indication of packaging materials. Based on customer feedback, we continue to make further improvements. For example, Otsuka Foods has redesigned allergen labelling by adding a list of allergens on the package in a separate location from the comprehensive list of ingredients and precautions. For Bon Curry for Children, illustrations have been added to make the information easier to understand, so that consumers can purchase it with peace of mind.

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

Given that society demands transparency in relationships between pharmaceutical companies and healthcare organizations, we are striving to ensure code adherence in order to fulfill our duty as a pharmaceutical company and ensure the practice of ethical, patient-oriented medical care.

1. Approach in the Nutraceutical and Consumer Products Businesses

The Nutraceutical Business contributes to solutions for social issues by providing creative products directed at maintaining and improving people’s health while offering useful health information. Otsuka Pharmaceutical has established the Scientific Affairs Department to gather and disseminate information about products, related knowledge and the latest academic information in order to provide appropriate information to consumers. To develop personnel who can help resolve social issues, we hold monthly training programs in three formats: group seminars, e-learning and satellite broadcasting.

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For details on the Declaration of Customer-centric Commitment, please visit our website: https://www.otsuka.com/en/company/customer/

Example of Improved Product: OS-1 Jelly

Enlarged cap diameter by 5 millimeters.

For packaging produced by group companies in Japan, with the exception of certain products such as those with space limitations, we ensure the understandability of labelling. In addition to information required by law, the following information is presented: instructions for storage after opening, precautions for use, an easy-to-read list of allergens contained (mandatory and recommended items), and a clear indication of packaging materials. Based on customer feedback, we continue to make further improvements. For example, Otsuka Foods has redesigned allergen labelling by adding a list of allergens on the package in a separate location from the comprehensive list of ingredients and precautions. For Bon Curry for Children, illustrations have been added to make the information easier to understand, so that consumers can purchase it with peace of mind.
Otsuka Group’s Environmental Policy
The Otsuka group of companies strives to advance as an essential company that contributes to the health of people worldwide. We will help to achieve a sustainable society by always taking account of the global environment and the value chain in which we operate.

The Otsuka Group Global Environmental Council
As an Otsuka group that contributes to the health of people worldwide, the Otsuka group works sincerely to reduce the global environment and seeks to contribute to the creation of a sustainable society that can protect nature and the future of the earth. The Otsuka Group Global Environmental Council comprises the group-wide coordinator at Otsuka Holdings, executive officers at each company, and a secretariat. Matters deliberated on by the council are approved by the Board of Directors of Otsuka Holdings, and shared as the environmental management policies of the Otsuka group. The council promotes initiatives that contribute to solutions to global social issues related to the earth’s environment.

Environment

1. Initiative for Efficient Energy Use and CO₂ Reduction
In Tokushima Prefecture, where a number of Otsuka group production sites are concentrated, we have installed cogeneration systems at Otsuka Chemical and Otsuka Pharmaceutical Factory. These systems generate electric power from natural gas, while converting waste heat into steam and hot water, which are then supplied to nearby group companies. Furthermore, the cogeneration system introduced in February 2020 at Otsuka Pharmaceutical Factory’s Toyama Factory supports our business continuity plan, reduces annual CO₂ emissions by approximately 1,800 tons, and contributes to energy efficiency and stable drug supply.

We are working to reduce CO₂ emissions by switching to renewable energy. In July 2019, we started introducing CO₂-free electricity, which is derived from renewable energy sources and does not emit CO₂, at Otsuka group factories and research centers in Tokushima Prefecture and at Otsuka Pharmaceutical’s Fukuroi Factory. In November 2019, we expanded its introduction to Otsuka Foods’ Shiga Factory, and overseas to Nutrition & Santé’s Spain Factory.

2. Validation of Otsuka Pharmaceutical and Taiho Pharmaceutical Goals under the SBT Initiative
Otsuka Pharmaceutical and Taiho Pharmaceutical have been validated under the Science Based Targets (SBT) Initiative.

Taiho Pharmaceutical has been validated under the Science Based Targets (SBT) Initiative.

In order to achieve these new goals, we will optimize energy use and introduce renewable energy, and continue to promote reduction of GHG emissions throughout the value chain.

3. Third-Party Verification of GHG Emissions
In order to improve the transparency and reliability of its environmental data, the Otsuka group has its GHG emissions scopes 1 and 2 (CO₂ emissions from energy sources, including energy consumption), and Scope 3 (Category 1) verified by third-party organizations. This helps us identify emissions trends and implement improvements. We will continue to expand the scope of verification and further enhance the reliability of our data.

Scope 3: Other indirect emissions

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</table>

1. Purchased goods and services
Scopes: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Chemical, and Otsuka Foods
Resource Recycling and Conservation

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

In order to realize both a sustainable society and ongoing corporate growth, a global shift to sustainable business models that grow without impacting the environment is necessary. To continue providing products that contribute to the health of people worldwide, the Otsuka group will raise resource efficiency throughout the value chain and build a sustainable system for recycling and conservation of resources, including biological resources.

1. Initiatives to Achieve Zero Waste

In fiscal 2019, the Otsuka group’s total global waste volume was 97,000 tons. The effective use amount including material recycling, composting, and heat recovery was 74,000 tons, or about 76% of the total.

Furthermore, the simple incineration volume was 5,000 tons (mainly in Japan) and the landfill volume was 11,000 tons (mainly overseas). Going forward, we will promote activities to reduce waste and disposal volumes together with group companies in Japan and overseas.

2. Initiatives Targeting the Issue of Plastic Waste

As an initiative aimed at solving the issue of plastic waste, we have formulated the Otsuka Group Plastic Policy to contribute to the sustainable recycling of resources. As a group that provides products that contribute to people’s health, the Otsuka group will continue measures to assure the safety and quality of containers and packaging.

Otsuka Group Plastic Policy

**Fundamental Concept**

PET bottles comprise the majority of plastic containers and packaging used for consumer products by our group companies. For this reason, we believe that by promoting PET bottle recycling, we can reduce our reliance on fossil fuel and thereby contribute to environmental conservation. Our plan is to use PET bottles manufactured from recycled and plant-based materials and increase the percentage of such sustainable resource use in our production processes globally to 50% by 2030 and 100 percent by 2050. Moreover, to advance PET material recycling, it is essential to recycle PET bottles for use as raw material. Together with our various stakeholders, we will advance our global efforts on proper collection and recycling of used PET bottles.

**Our Vision for 2050**

For our entire line of consumer products, we will endeavor to use packaging that supports a sustainable society:

- No use of plastics made from petroleum-based materials
- Promote use of recycled, plant-based, and biodegradable materials
- Promote use of recyclable packaging

**Our Goal for 2030**

- Achieve a 50 percent or higher content of recycled and plant-based materials in our PET bottles.
- Introduce alternative packaging (e.g., paper) and increase use of cases for our drink products.
- Step up promotion of drink bottle recycling by introducing recyclable packaging through a zero-waste sales and circular distribution model, which also includes the use of sports bottles for our powder products.
- We will promote the use of alternative packaging and concurrently pursue using more recyclable materials for drink containers.

Water Conservation

FY 2030 Goal: Improvement of water use efficiency by 15% compared to FY 2019

Since its establishment, the Otsuka group’s operations have had a deep connection to water, a resource essential to life. Through products that use water as a raw material, we have actively contributed not only to the treatment and prevention of diseases, but also the maintenance and promotion of health. We therefore recognize water as an important resource, and consider its conservation to be a critical global issue. Moreover, water resources are uniquely distributed across different countries and regions, each of which faces different risks. The Otsuka group therefore cooperates with all stakeholders, and conducts ongoing water conservation initiatives from intake to discharge (including cultivation of water resources, conscientious use and clean return), in the aim of sustainable water use.

Evaluating Water Risk at Production Sites

Considering environmental risk in each region is also important to sustainable growth in the diverse business models of the Otsuka group operating around the world. Since 2017, the Otsuka group has conducted water risk assessments at all production sites using the water risk assessment tool “Aqueduct,” developed by the World Resources Institute (WRI), so as to understand and minimize the impact of such risk on water-related business activities.

Going forward, we will conduct more specific assessments and promote activities tailored to each region that target the effective management and use of water, with the aim of conservation and sustainable use of water resources.

Environmental Friendly Products of the Otsuka Group

Going beyond making our products themselves low impact, in development, we consider environmental impact throughout the value chain, from raw material procurement to disposal, as well as the needs of the times resulting from changes in society. In this way, we contribute to solutions to global environmental issues and increasingly diverse social issues.

A unique formulation allows POGARI SWEAT ICE SLURRY to be stored at room temperature

We developed POGARI SWEAT ICE SLURRY with a focus on core body temperature regulation to support active people in hot environments. The unique formulation of this drinkable ice product allows it to be stored at room temperature and conveniently frozen before use. Even if it melts, the liquid can be returned to a slurry state by refreezing. This also enables energy savings when transporting or storing the product.

Bon Curry can be warmed in the microwave while still in the box

Launched in 1988, Bon Curry was the world’s first commercial retort pouch food product and can be heated in the microwave while still in the box. It saves consumers the time and trouble of boiling water or putting the curry on a plate to warm it. This product is environmentally friendly because it does not require open flame or water for preparation.*

The world’s first quad-chamber infusion bag

Otsuka Pharmaceutical Factory develops products under its management vision of being “The Best Partner in Clinical Nutrition.” It is focusing above all on the development of kit products that are easy for healthcare workers to use, and which also reduce medical errors and the risk of infection. Otsuka Pharmaceutical Factory was behind the development of the first-ever quad-chamber bag, which is used for ELAWIPS, a high-calorie infusion vitamin mixture containing glucose, electrolytes, amino acid, multivitamin, and trace elements. Its groundbreaking design makes it possible to aseptically prepare the mixture with a single push. It also saves resources, enables efficient transportation and reduces disposal waste.
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 responsibilities and authorities to enhance the profitability and capital investment efficiency in order to promote the sustainable growth of the Company and the increase of corporate value over the medium to long term. The Company secures its soundness and establishes the solid corporate governance structure living up to social expectations by ensuring that the Audit & Supervisory Board and its members, which are independent from the Board of Directors, can audit the Directors’ performance of their duties in collaboration with the Accounting Auditor, as well as the Internal Audit Department.

1. Corporate Organization

As a company with an audit and supervisory board as defined by the Companies Act, the Company has established a Board of Directors and an 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.

<table>
<thead>
<tr>
<th>Initiatives to Strengthen Corporate Governance</th>
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2. Board of Directors Meetings

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

3. Director Selection Criteria

The Company aims to become “an indispensable contributor to people’s health worldwide” by targeting sustainable growth and enhanced corporate value over the medium to long term. Toward this aim, the Company works to ensure the overall diversity of directors, and appoints people with the insight, expertise, and experience needed to realize and maintain appropriate and effective corporate governance. For internal directors in particular, we comprehensively evaluate the experience, expertise, insight, and other attributes of candidates to ensure that they have the qualities needed to implement the group’s corporate philosophy, Code of Business Ethics, and management strategies.

4. Corporate Governance Committee

In February 2017, the Company established the Corporate Governance Committee with the aim of increasing transparency and objectivity in management. As an advisory body to the Board of Directors, the committee discusses matters relating to corporate governance, including the nomination of directors and Audit & Supervisory Board members, and the remuneration system and standards for directors, and reports the results of its deliberations to the Board of Directors. The committee consists of the president, the director in charge of administration, and all four outside directors. The president serves as the chair of the committee.

Content of Deliberations

(1) Nomination

The Corporate Governance Committee discusses the validity and fairness of matters related to the appointment and dismissal of directors and Audit & Supervisory Board members, and reports to the Board of Directors. Regarding candidates for Audit & Supervisory Board members, the committee obtains approval from the Audit & Supervisory Board prior to reporting to the Board of Directors. Candidates are those put forward by the representative director(s).

(2) Remuneration

The Corporate Governance Committee discusses matters related to the remuneration system and standards for directors and Audit & Supervisory Board members, and reports to the Board of Directors.

(3) Corporate Governance Structure

In addition, the Committee deliberates on matters related to the enhancement of the corporate governance structure, and reports to the Board of Directors as necessary.

5. Audit & Supervisory Board and Its Members

Audit & Supervisory Board members attend and express opinions at meetings of the Board of Directors, and monitor the performance of duties of directors in terms of legal compliance and soundness of management through audits. In striving to improve the effectiveness of audits, Audit & Supervisory Board members also share information and exchange opinions as appropriate with relevant departments, including the Internal Audit Department, Internal Control Department, Administration Department, and Finance and Accounting Department, as well as the accounting auditor.

6. Evaluation of Effectiveness of Board of Directors

From January through February every year, the Company conducts a questionnaire survey of all directors and Audit & Supervisory Board members. Results of the survey are reviewed by a company attorney, and then reviewed and evaluated at the Board of Directors meeting in March. Questionnaire items are as follows.

(1) Composition of the Board of Directors

(2) Each director’s understanding and knowledge of business fields and specific management strategies and plans
(3) Cooperation with outside directors
(4) Cooperation with the Audit & Supervisory Board
(5) Operation of Board of Directors meetings
(6) Governance-related matters
  i. Function of the Board of Directors in determining the direction of management strategy
  ii. Monitoring of each business with respect to the execution of management strategy
  iii. Understanding of the perspectives of major investors and stakeholders
  iv. Risk management
  v. Cooperation and information sharing with each operating company
(7) Support system for outside directors
(8) Overall functioning of the Board of Directors from the perspective of effectiveness

Summary of Evaluation in Fiscal 2019
The results of the analysis and evaluation of the overall effectiveness of the Board of Directors in fiscal 2019 are summarized below.

There was an increase in opinions stating improvement from the previous year regarding the 12 items in the questionnaire. The opinions noted particular improvement in (3) Cooperation with outside directors, (4) Cooperation with the Audit & Supervisory Board, (6) i. Function of the Board of Directors in determining the direction of management strategy and (6) ii. Monitoring of each business with respect to the execution of management strategy.

With regard to (5) Operation of Board of Directors meetings, there was agreement that deliberations have improved. However, issues were identified, such as criteria for whether items should be deliberated by subsidiaries or be deliberated and subject to resolution of the Board of Directors, appropriate allocation of deliberation time, and early provision of reference materials. This confirms the need to further review matters relating to this item.

On the basis of this evaluation, we believe that the Company's Board of Directors is functioning appropriately from the perspective of effectiveness. Nonetheless, we will strive to make further improvements on issues that have been identified through evaluation and review. In addition, we will work to strengthen corporate governance by discussing best practices in our role as a holding company, and in cooperating with and monitoring subsidiaries.

7. Independence Criteria for Independent Officers
When selecting outside directors and outside Audit & Supervisory Board members, the Company looks for individuals with a wealth 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. The Independence Standard Committee, comprised of directors, is established in our Corporate Governance Guidelines, and forms the basis for judgements on the independence of outside directors.

In addition, we require that they have not previously been engaged in the execution of operations at any of our group companies. Furthermore, given that all outside directors and outside Audit & Supervisory Board members satisfy public requirements of independent directors, the Company has registered them as such with the TSE.

8. 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 of the Company and its affiliated companies. The department submits audit reports to the president, directors, and Audit & Supervisory Board members. Where there is need for improvement, the department recommends remedial actions and later confirms its implementation, thereby contributing to the optimization of business execution. The department also shares information and cooperates in audits by Audit & Supervisory Board members and the accounting auditor.

9. 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 also works in cooperation with the Internal Audit Department to continuously monitor the status of operations. This is the basis of an internal control system under which management personnel can be reliably evaluated.

Our basic approach to the internal control system and its current status are described in the Corporate Governance Report that we submit to the TSE (available only in Japanese).

10. Accounting Audit
The Company has signed an auditing agreement with Deloitte Touche Tohmatsu LLC as the accounting auditor to audit its accounts from a fair and impartial standpoint. The certified public accountants that audited the Company's accounts were Yutaka Manzu, Koichi Niki, and Hirofumi Otani. They were assisted by eight other certified public accountants and six other individuals. All of the certified public accountants that audited the Company's accounts have done so for less than seven consecutive years, therefore that description is omitted.

11. Succession Plan
The Company continues to develop and implement human resource development programs to identify and promote talented personnel early and systematically nurture next-generation management candidates equipped with the qualities and skills called on by the corporate philosophy. The status of these programs is regularly reported to the Board of Directors.

Skill Matrix for Directors and Audit & Supervisory Board Members
In order to establish an effective corporate governance structure that supports business, the Company appoints individuals with wide-ranging business experience, advanced expertise in broad fields, and extensive knowledge, as directors and Audit & Supervisory Board members. The table below summarizes areas of experience and expertise of directors and Audit & Supervisory Board members.

<table>
<thead>
<tr>
<th>Skill Matrix for Directors and Audit &amp; Supervisory Board Members</th>
<th>Rationale for selection2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global business</td>
<td>Technology, R&amp;D, production</td>
</tr>
<tr>
<td>Strategic planning, marketing, sales</td>
<td>Finance, accounting</td>
</tr>
<tr>
<td>Internal controls, risk management</td>
<td>Company analysis</td>
</tr>
<tr>
<td>Healthcare administration, public health</td>
<td>Major qualifications, etc.</td>
</tr>
</tbody>
</table>

1. For all outside directors and outside Audit & Supervisory Board members, given no risk of conflict of interest with shareholders, the Company believes such outside officers qualify as an independent director/committee.
2. Attendance for Board of Directors meetings and Audit & Supervisory Board meetings by Mayo Mita is not listed because she was newly appointed as an outside director at the 12th General Meeting of Shareholders held on March 27, 2020.
Remuneration for Directors and Audit & Supervisory Board Members

The Company’s remuneration plan for directors and Audit & Supervisory Board members is designed to achieve sustainable growth and enhanced corporate value over the medium to long term for the group while also ensuring that functions such as business execution and management supervision are exercised appropriately, maintaining transparency and fairness. The Company’s basic approach to remuneration for directors and Audit & Supervisory Board members is as follows.

1. Remuneration Levels
Considering the need to acquire and motivate outstanding personnel who will take responsibility for the Company’s global business activities, the Company sets remuneration levels fully commensurate with the roles and responsibilities expected of such personnel.

2. Remuneration System
With regard to remuneration for directors responsible for business execution, the Company has formulated a remuneration system that is closely linked to performance in individual fiscal years, as well as over the medium to long term, while emphasizing sustainable enhancement of corporate value. In addition to cash remuneration, the Company also provides share-based payments more closely linked to shareholder value. Outside directors and Audit & Supervisory Board Members are paid fixed remuneration; they are not paid any remuneration that varies according to performance.

3. Governance of Remuneration-related Decisions (Activities of the Remuneration Committee and the Board of Directors)
Decisions related to remuneration for directors and Audit & Supervisory Board members are made by the Board of Directors based on a report from the Corporate Governance Committee, an advisory body to the Board of Directors. The committee deliberates on matters including the remuneration system and levels of remuneration. When deciding on remuneration, efforts are made to enhance objectivity through such means as utilizing external data.

In determining remuneration for directors and Audit & Supervisory Board Members in the current term, the Board of Directors and the Corporate Governance Committee deliberate a number of times. The Board of Directors makes final decisions after receiving the Corporate Governance Committee’s report that those decisions are appropriate.

In addition, following extensive study by the Board of Directors and the Corporate Governance Committee, the decision was made to design and implement a restricted stock-based compensation system starting fiscal 2019.

4. Composition of Remuneration
a) Remuneration for directors of Otsuka Holdings (holding company of the Otsuka group)
Remuneration for directors (excluding outside directors) of the Company consists of fixed remuneration according to title or position, bonuses linked to results of operations (short-term incentive), as well as stock-based compensation (medium-to-long-term incentive). Remuneration for outside directors and Audit & Supervisory Board members consists only of fixed remuneration.

b) Composition of remuneration for directors (excluding outside directors)
Performance-linked remuneration as a percentage of total remuneration varies according to the Company’s single-year and medium-to-long-term consolidated results of operations. The system emphasizes medium-to-long-term enhancement of corporate value. Performance-linked bonuses are designed to be variable over the range of 0–100% of fixed remuneration, and stock-based compensation over the range of 0–100% of fixed remuneration. Maximum performance-linked remuneration as a percentage of total remuneration is 66% (200% of 300% total).

c) Remuneration for directors of subsidiaries (operating companies of the Otsuka group)
Remuneration for directors of subsidiaries that are operating companies is determined based on their duties and responsibilities (including execution of business of operating companies based on group strategies formulated by the Company, formulation of strategies for operating companies, and strengthening corporate governance) and is not to exceed the cap on director remuneration resolved at the General Meeting of Shareholders.

It should be noted that the restricted stock-based compensation system newly implemented in fiscal 2019 will also apply to about 40 directors (excluding outside directors) of some of the group’s major subsidiaries.

Regarding Directors’ Conflict of Interest
All operational judgements and decisions are not to be made in relation to the interests of individuals, but in the best interests of the Otsuka group. The Otsuka group has established the Otsuka Group Global Conflict of Interest Policy to prevent such conflicts of interest. It also applies to directors. ➔ Page 64, Compliance
### Directors and Audit & Supervisory Board Members

**As of March 27, 2020**

#### Directors

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Start Date</th>
<th>End Date</th>
<th>Profile/Notes</th>
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</thead>
<tbody>
<tr>
<td>Ichiro Otuka</td>
<td>Chairman and Representative Director</td>
<td>Mar. 1960</td>
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<tr>
<td>Tatsuo Higuchi</td>
<td>President and Representative Director</td>
<td>Mar. 1977</td>
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<tr>
<td>Yoshio Matsuo</td>
<td>Executive Director</td>
<td>Apr. 1984</td>
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<tr>
<td>Yuko Makino</td>
<td>Executive Director</td>
<td>Apr. 1985</td>
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<tr>
<td>Noriko Toge</td>
<td>Executive Director</td>
<td>Apr. 1985</td>
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<tr>
<td>Makoto Inoue</td>
<td>Executive Director</td>
<td>Apr. 1986</td>
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<tr>
<td>Yoshio Shiozawa</td>
<td>Executive Director</td>
<td>Apr. 1986</td>
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<tr>
<td>Tatsuo Ichimura</td>
<td>Executive Director</td>
<td>Apr. 1986</td>
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<tr>
<td>Ko Sekiguchi</td>
<td>Executive Director</td>
<td>Apr. 1986</td>
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#### Outside Directors

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<tr>
<th>Name</th>
<th>Position</th>
<th>Start Date</th>
<th>End Date</th>
<th>Profile/Notes</th>
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</thead>
<tbody>
<tr>
<td>Yuko Toba</td>
<td>Outside Audit &amp; Supervisory Board Director</td>
<td>Mar. 1979</td>
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<tr>
<td>Hiroshi Sugawara</td>
<td>Outside Audit &amp; Supervisory Board Director</td>
<td>Mar. 1979</td>
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#### Audit & Supervisory Board Members

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<th>Name</th>
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<th>Start Date</th>
<th>End Date</th>
<th>Profile/Notes</th>
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<tbody>
<tr>
<td>Makoto Inoue</td>
<td>Executive Director</td>
<td>Apr. 1986</td>
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**Profile**

- **Ichiro Otuka**: Chairman and Representative Director of Otsuka Holdings Co., Ltd. since March 1960.
- **Yoshio Matsuo**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1984.
- **Yuko Makino**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1985.
- **Noriko Toge**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1985.
- **Makoto Inoue**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1986.
- **Ko Sekiguchi**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1986.
- **Yukio Shiozawa**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1986.
- **Tatsuo Ichimura**: Executive Director of Otsuka Pharmaceutical Co., Ltd. since April 1986.
- **Yoko Wachis**: Outside Audit & Supervisory Board Director since March 1979.
- **Hiroshi Sugawara**: Outside Audit & Supervisory Board Director since March 1979.

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**Notes**

- **Ichiro Otuka**: Director of the Organic Materials & Research Division, Otsuka Pharmaceutical Co., Ltd. (current)
- **Yoshio Matsuo**: Director of the Marketing & Development Division, Otsuka Pharmaceutical Co., Ltd. (current)
- **Yuko Makino**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
- **Noriko Toge**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
- **Makoto Inoue**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
- **Ko Sekiguchi**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
- **Yoko Wachis**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
- **Hiroshi Sugawara**: Director of the Corporate Department, Otsuka Pharmaceutical Co., Ltd. (current)
Messages from Outside Directors

Enhancement and Expansion of Businesses Critical to Life through Stronger Governance

Each year, members of the Board of Directors are asked to evaluate the Board’s effectiveness and give a detailed account of the roles of the Board and each of its members. It is a robust assessment. As a medical doctor, I am expected to contribute opinions based on my broad expertise from many years of involvement in clinical medicine, public health, and healthcare administration, and I have strived to live up to those expectations.

Healthcare is an essential aspect of social infrastructure and everybody needs healthcare. Given that healthcare is critical to life, the level of quality must be paramount, while other requirements and demands are also significant. Healthcare costs rise year after year. It is therefore essential to make the most effective use of finite resources. In Otsuka’s Pharmaceutical Business, this entails the efficient creation of drugs, medical devices, and diagnostic agents that in turn supports their efficient provision to patients. In the Nutraceutical Business, it means creating products that help people to maintain or improve their well-being. Going forward, Otsuka Holdings must continue to offer value to society in both of these areas.

Yukio Matsutani
Outside Director

Meeting the Expectations of Stakeholders Worldwide Based on Sincerity

The provision of information prior to Board meetings has been enhanced, including its timing. Important information is shared at individual briefings, and explanations are provided regarding the status of group companies and other operational data. I feel that one of the strengths of Otsuka’s corporate culture is its embodiment of integrity and humility. This goes a long way to earning the trust of customers and business partners. Otsuka is committed to providing consumers and patients with the solid value that generates revenues and profits.

Results in the Pharmaceutical Business have been excellent, but from a medium-to-long-term perspective, a look at the drug pipeline indicates there is no room for complacency. It is also vital that Otsuka becomes a truly global company, and evolves to the next stage rather than simply operating as a collection of companies. Only by adopting this approach can Otsuka develop a clear roadmap for the future.

Ko Sekiguchi
Outside Director

High Expectations for Otsuka’s Contributions to a 100-Year Lifespan through Preventive Medicine

The chairman has ensured that Board meetings are a forum where members can discuss matters freely, which fosters meaningful discussions. Furthermore, I believe that the appointment of a new president at Otsuka Pharmaceutical has strengthened the governance framework.

In China, it has been a long-held belief that herbal medicines and a proper diet share similar principles, and today it is widely accepted everywhere that a balanced diet is the basis of good health. The Otsuka group’s strong footing in food and nutrition may be attributable to its belief in this philosophy. Otsuka is doing good work with respect to safety and security, and consumers appreciate that. We are approaching an age when it will be common for people to live to 100, and preventive medicine will play a vital role in that. Not many companies are able to offer solutions in both treatment and prevention solutions. Indeed, many businesses give up if they are unable to make a quick profit, but the Otsuka group is ready for the long haul; even if a product does not sell well initially, Otsuka has the patience and determination to go the distance. I hope that Otsuka will continue in this vein, because it will benefit society.

Yoshihisa Aoki
Outside Director

Sharing Otsuka’s Unique Corporate Story Will Build Broad Stakeholder Loyalty

My first impression of the Otsuka group was its uniqueness. Operating for many years in pharmaceuticals and healthcare, as well as food and nutrition, I expect it to sustain its operations long into the future. Indeed, with its centenary approaching in 2021, I look forward to seeing how Otsuka advances into its second century.

I see my role as a bridge between company management, and analysts, shareholders, and investors. As an outside director, I hope to support Otsuka’s development by pointing out opportunities to management and diligently raising concerns as necessary.

When an enterprise comprises such a broad range of businesses as Otsuka, I believe it is important to identify the common threads that unite them all. The key is how to effectively convey that story not only to shareholders and the investment market, but also to customers, consumers, and employees. If Otsuka is able to convey the story of its passion, it is sure to acquire many more long-term fans.

Mayo Mita
Outside Director
Guiding Principles: Synopsis

**1. Otsuka Group Global Anti-Corruption Policy**
The Otsuka Group Global Anti-Corruption Policy embodies and reiterates our steadfast commitment to conducting business with integrity and in compliance with all relevant anti-corruption laws. This Policy outlines how to prevent, detect, and deter violations of anti-corruption laws. It sets forth our global minimum standards regarding the prevention of corruption and applies to all our worldwide business operations.

**2. Otsuka Group Global Conflict of Interest Policy**
The Otsuka group recognizes conflicts of interest between the group and individual employees as a matter that could impact the integrity of the organization, and one that has a great bearing on the group’s future. Based on this thinking, we formulated the Otsuka Group Global Conflict of Interest Policy to prevent such conflicts and we are working to instill the policy at a global level.

**3. Otsuka Group Global Privacy Policy**
In recent years, many countries have enacted privacy protection legislation, such as the European Union’s General Data Protection Regulation (GDPR) implemented in May 2018. The Otsuka group is working to strengthen privacy protection. In addition to formulating the Otsuka Group Global Privacy Policy to define our stance and guiding principles on privacy protection, we establish related rules and review management systems in accordance with the laws and regulations related to privacy protection in each country.

**4. Training System**
The Otsuka group conducts universal compliance training at least once annually based on the content of the Global Code of Business Ethics, the Global Anti-Corruption Policy, and the Global Conflict of Interest Policy. Employees at subsidiaries attend training, and materials are available in Japanese, English, Chinese, and Indonesian. Furthermore, the implementation status of training is regularly reported to the Board of Directors of Otsuka Holdings.

**5. Monitoring**
As a holding company whose role is to maximize the Otsuka group’s corporate value, Otsuka Holdings has established a system to ensure appropriate business operations from the perspective of the group as a whole. We have established a system for facilitating cooperation in the Otsuka group. Under this system, affiliated companies report to Otsuka Holdings as necessary regarding items specified in the Affiliated Company Management Regulations, and obtain approval on relevant important items.

Examples of overseas initiatives include the appointment of compliance officers at each group company in Asia and the holding of regular meetings for sharing the status of progress in each country. The director in charge of compliance also visits companies to gather information and offer suggestions on how improvements may be made.

In addition, an Internal Audit Department under the direct authority of the president has been established. It conducts regular 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 Otsuka Holdings and its affiliated companies. The department submits its audit reports to the president, directors, and Audit & Supervisory Board members. In cases where it finds the need for improvements, the department issues improvement advisories. It then follows up to check the implementation status of measures and ascertain that the execution of duties has been suitably improved. In addition, the department shares information with Audit & Supervisory Board members and the accounting auditor and coordinates a unified stance.

**6. Whistleblowing Hotline**

**a) Internal Whistleblowing Hotline**
At Otsuka Holdings and its overseas group companies, we have established an internal whistleblowing hotline within the group and at the offices of an attorney that can be accessed safely and anonymously. Through this hotline, we work to ensure that any improper acts, including acts of bribery, as well as violations of policies, laws and regulations, can be quickly uncovered and corrected. Rules for accepting reports extend beyond full-time employees to include contract, dispatched, and part-time employees. Information about whistleblowers and their reports is strictly managed in order to prevent any negative repercussions. Information on the operational status of the internal whistleblowing hotline at major group companies is regularly reported at meetings of the Board of Directors of Otsuka Holdings.

**b) External Inquiries and External Whistleblowing Hotline**
Otsuka Holdings and its major group companies have established a whistleblowing hotline that accepts inquiries and opinions from external stakeholders and general customers. Furthermore, certain channels of the hotline also accept anonymous consultations and reports.

**7. Due Diligence**
Each group company has established a due diligence policy and conducts due diligence for new business partners as needed to evaluate corruption-related risk.

Compliance

Legal compliance is the cornerstone of all our business activities. The Otsuka group maintains high ethical standards and conducts its business activities with integrity in order to secure the trust of all stakeholders and achieve sustainable growth.

Universal compliance training participation rate: 98.4%

**Approach**
We have established the Otsuka Group Global Code of Business Ethics and we openly convey information about our stance on related initiatives on our website in the form of a message from the president of Otsuka Holdings. Furthermore, we have formulated the Otsuka Group Global Anti-Corruption Policy, which expresses our stance against corruption at all sites worldwide; the Otsuka Group Global Privacy Policy, which defines our stance and guiding principles on privacy protection. These policies form the basis for conducting our business with high ethical standards.

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Otsuka Holdings Co., Ltd. INTEGRATED REPORT 2019

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71
Tax Compliance

The Otsuka group complies with the Otsuka Group Global Code of Business Ethics, the group’s tax policy, country-specific laws, regulations and tax treaties, as well as international taxation rules, and does not engage in transactions designed to evade the payment of taxes, but carries out the appropriate filing and payment of taxes in each country. We endeavor to accurately disclose information and ensure a degree of transparency and trust when dealing with tax authorities in each country. The complexity of tax oversight increases as our businesses become more global. By continuously updating information and engaging in prior consultations with tax experts where necessary, we are appropriately responding in order to minimize tax risk.

1. Correspondence with Tax Authorities

The Otsuka group engages in constructive relationships with tax authorities in the 31 countries/regions in which it operates. We will continue to improve the reliability of tax data and establish systems to provide it promptly.

2. Transfer Pricing Policy

The Otsuka group calculates transfer prices based on the OECD guidelines that were created for the prevention of double taxation and fair application of the transfer price tax system, as well as each country’s transfer price tax system, and makes efforts to ensure proper transactions between related parties. In recent years, the OECD has issued an action plan on base erosion and profit shifting (BEPS), in which multinational companies engage in international transactions that lead to double non-taxation. We will properly execute our obligations to make submissions to relevant authorities. Also, when necessary, we make use of advance pricing agreements (APAs) to obtain ahead-of-time consensus from tax authorities.

3. Governance

We work to maintain and improve tax-related governance, recognizing that this contributes to the enhancement of corporate value. To this end, under the active involvement of the CHO, we are strengthening cooperation between departments and operating companies as well as securing and training capable human resources, thereby maintaining an appropriate system that enhances tax compliance and reduces tax risks. Furthermore, we have established reporting obligations to the Board of Directors and the Audit and Supervisory Committee regarding the above-mentioned policies and processes, as well as their ongoing implementation and maintenance.

Anti-Corruption Due Diligence

Due diligence includes investigations into the third-party supplier’s background, reputation, financial records, codes of conduct and training, and business conduct as well as written agreements and monitoring controls. The following circumstances typically necessitate anti-corruption due diligence: (a) engaging the services of a third-party supplier; (b) entering into a joint venture with another entity; and (c) merging with or acquiring another entity. We perform due diligence before and after proceeding with the proposed business transaction, continuously evaluating the third-party supplier’s adherence to relevant anti-corruption laws.

We conduct risk-based and risk-based due diligence. The due diligence process must be a fact-based inquiry closely tailored to the specific business operations of the third-party supplier. We define the proper level of due diligence for each third-party supplier, depending on key risk factors (e.g., the industry, geographic location, reputation, beneficial ownership, professional capability, experience, financial standing and creditability of the third-party supplier and the history of that third-party supplier’s compliance with applicable anti-corruption laws and regulations, the scope of the services performed).

Not intended to be a one-time event, due diligence should be considered an ongoing process. We must periodically re-examine our relationship with third-party suppliers. The frequency of the re-examination may depend on the level or risk presented by the party as well as the context in which they are engaged.

Risk Management

The Otsuka group carries out risk management under the supervision of top management based on the recognition that pursuing management efficiency and controlling the risks inherent in business activities is important to enhancing corporate value.

1. Business Continuity Planning and Management

The Otsuka group has business continuity plans (BCPs) in place to ensure that the group continues to operate as effectively as possible in order to maintain the stable supply of products, even when large-scale earthquakes and disasters strike. From the perspective of business continuity management (BCM), Otsuka Holdings and its group companies are cooperating to construct a group-wide business continuity framework. In August 2012, we acquired ISO 22301 certification for the production and stable supply of pharmaceutical products, beverages, and foods, and we have since gradually expanded the scope of certification. We acquired additional certification for the stable supply of intravenous solutions in April 2015, and for the stable supply of anticancer agents in May 2016. The acquisition of ISO 22301 certification demonstrates that our organization is fully equipped and prepared from a BCM standpoint.

Through collaboration mainly between Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taho Pharmaceutical, and Otsuka Warehouse, the Otsuka group is making every effort to strengthen its countermeasures and systems so that the group as a whole can effectively continue its business activities and thereby ensure stable product supply even during times of disaster. In 2018, major group companies jointly conducted a desktop simulation drill for the scenario of an earthquake with an epicenter directly below Tokyo. Then in 2019, they jointly conducted another desktop simulation drill; this time for the scenario of a typhoon passing directly over western Japan. These drills provided opportunities for testing cooperation systems under close-to-realistic conditions, with a focus on ensuring stable product supply.

2. Risk Management Training

Risk management training is held annually for directors, Audit & Supervisory Board members, executive officers, and department heads of major group companies. Training includes simulation drills and lectures by outside experts, and involves discussions and reviews on the subject of domestic and overseas risk, referencing serious incidents and other matters. Topics include initial response and coordination of information among the group when a crisis occurs, measures to ensure business continuity, and corporate social responsibility.

3. Information Security

The Otsuka group has established the Otsuka Group Global Security Policy as its basic policy on information security. We endeavor to ensure shared awareness of the policy at all group companies, including overseas subsidiaries. In striving to raise the level of, and constantly improve, comprehensive security across the group, we set up the Otsuka Group Information Security Committee to examine specific measures and to share up-to-date information with regard to information security based on the policy. In order to counter the risk of cyberattacks, the Otsuka group employs a number of measures, such as arranging system security audits by external specialists, diagnosing website vulnerabilities, conducting drills related to targeted email attacks, and monitoring posts on social media. The group also conducts regular emergency drills with a focus on the core systems that construct data. In addition, we have built capabilities for responding to cybersecurity emergency situations, including the establishment of the Computer Security Incident Response Team (CSIRT), which prevent the occurrence of damage from cyberattacks targeting personal information and trade secrets held by respective group companies.

Working with Third-Party Suppliers

Conducting our business according to rigorous legal, ethical and professional standards, we require the same standards from all third-party suppliers who perform services on Otsuka’s behalf. Otsuka can be held liable for the actions of the third parties who act as intermediaries for and on behalf of Otsuka in the conduct of business dealings. Prohibitions that apply to our employees apply equally to all individuals and entities acting on our behalf. Accordingly, our commitment to anti-corruption activities includes use of special care in our business dealings through third-party suppliers or intermediaries.

At the outset of our relationship with third-party suppliers, we should clearly articulate and effectively communicate our policy against corruption as well as our commitment to transparent and responsible business conduct. We expect third-party suppliers to share and uphold this dedication.

We will re-examine our business relationship with third-party suppliers who fail to ensure compliance with the relevant laws and regulations and this policy. Upon any indication of misconduct, we all have a duty to properly execute our obligations to make submissions to tax authorities in the 31 countries/regions in which it operates. The Otsuka group engages in constructive relationships with tax authorities where necessary, we are appropriately responding in order to minimize tax risk.

Risk Management System

In order to reform the risk management system for the Otsuka group, we have put in place the Risk Management Policy and set up a Risk Management Committee. The committee comprises the President and Representative Director as the chair, the director in charge of administration as the vice chair, as well as the information disclosure officer and the internal control officer. Leveraging the controls operated by each risk management department, the Risk Management Committee assesses and comprehensively manages risks that could jeopardize the sustainable enhancement of group value.

Responsibilities of the Risk Management Committee

The Risk Management Committee examines group risk management policies, coordinates between all companies and departments and issues instructions when a risk manifests, reports risk information to the Board of Directors, issues instructions to all companies, and promotes compliance.

Approach

The Otsuka group individually assesses risks in each of its businesses. Risk management officers are responsible for analyzing and evaluating risk, and formulating and executing action plans so that each organization can meet its objectives and targets. We also periodically implement 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 another part of this approach. Furthermore, we regularly hold drills to prepare for unexpected events such as disasters.

(Except from the Otsuka Group Global Anti-Corruption Policy)
Visit the Otsuka Holdings website for major CSR data: https://www.otsuka.com/en/arhd_activity/download/MajorCSRData_en.pdf
Main Data
With effect from fiscal 2016 (ended December 31, 2016), Otsuka adopted International Financial Reporting Standards (IFRS). Information for fiscal 2015 (ended December 31, 2015) is also presented in line with IFRS.

1. Line items are based on IFRS.
2. SG&A expenses under J-GAAP are presented as total expenses less R&D expenses. The Company believes that this information is useful to investors in comparing the Company’s financial results under J-GAAP with those under IFRS.
3. Excluding impairment losses.
4. Business profit = Revenue − Cost of sales − Selling, general and administrative expenses + Share of profit of associates − R&D expenses
5. 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.
6. As of December 31, 2019, the Company finalized provisional accounting treatments for business combinations. This is reflected in the presentation of figures for the year ended December 31, 2018.
8. Number of employees at 167 companies including Otsuka Holdings Co., Ltd. and its subsidiaries (as of December 31, 2019).

### Results of Operations

<table>
<thead>
<tr>
<th>Item</th>
<th>J-GAAP</th>
<th>IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong> (¥ billion)</td>
<td>¥1,154.6</td>
<td>¥1,427.4</td>
</tr>
<tr>
<td>Selling, general and administrative expenses</td>
<td>¥457.4</td>
<td>617.5</td>
</tr>
<tr>
<td>Business profit before R&amp;D expenses</td>
<td>¥697.2</td>
<td>710.1</td>
</tr>
<tr>
<td>Ratio of business profit before R&amp;D expenses to revenue (%)</td>
<td>59.0%</td>
<td>50.0%</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>¥159.2</td>
<td>237.8</td>
</tr>
<tr>
<td>R&amp;D ratio (%)</td>
<td>13.8%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Business profit</td>
<td>¥538.0</td>
<td>472.3</td>
</tr>
<tr>
<td><strong>Operating profit</strong> (¥ billion)</td>
<td>¥148.7</td>
<td>271.7</td>
</tr>
<tr>
<td><strong>Profit attributable to owners of the Company</strong> (¥ billion)</td>
<td>¥120.2</td>
<td>187.2</td>
</tr>
</tbody>
</table>

### Financial Position

<table>
<thead>
<tr>
<th>Item</th>
<th>J-GAAP</th>
<th>IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total assets</strong> (¥ billion)</td>
<td>¥1,666.8</td>
<td>¥2,575.3</td>
</tr>
<tr>
<td><strong>Total equity</strong> (¥ billion)</td>
<td>1,222.8</td>
<td>1,727.4</td>
</tr>
<tr>
<td><strong>Ratio of equity attributable to owners of the Company to total assets</strong> (%)</td>
<td>72.5%</td>
<td>68.4%</td>
</tr>
<tr>
<td><strong>ROE (%)</strong></td>
<td>7.8%</td>
<td>4.7%</td>
</tr>
</tbody>
</table>

### Cash Flows

<table>
<thead>
<tr>
<th>Item</th>
<th>J-GAAP</th>
<th>IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net cash flows from operating activities</strong> (¥ billion)</td>
<td>¥147.6</td>
<td>¥257.9</td>
</tr>
<tr>
<td><strong>Net cash flows from (used in) investing activities</strong> (¥ billion)</td>
<td>(107.6)</td>
<td>(422.6)</td>
</tr>
<tr>
<td><strong>Free cash flows</strong> (¥ billion)</td>
<td>40.0</td>
<td>(164.7)</td>
</tr>
<tr>
<td><strong>Dividends</strong></td>
<td>¥45</td>
<td>¥100</td>
</tr>
<tr>
<td><strong>Dividend payout ratio (%)</strong></td>
<td>27.2%</td>
<td>51.3%</td>
</tr>
</tbody>
</table>

### Common Stock, Stock Price

<table>
<thead>
<tr>
<th>Item</th>
<th>J-GAAP</th>
<th>IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of shares outstanding at year-end</strong> (Thousand shares)</td>
<td>557,836</td>
<td>557,836</td>
</tr>
<tr>
<td><strong>Stock price at year-end</strong> (¥)</td>
<td>2,450</td>
<td>4,317</td>
</tr>
</tbody>
</table>

### Number of Employees

<table>
<thead>
<tr>
<th>Item</th>
<th>J-GAAP</th>
<th>IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong> (Persons)</td>
<td>24,595</td>
<td>31,940</td>
</tr>
<tr>
<td>Japan</td>
<td>13,808</td>
<td>14,082</td>
</tr>
<tr>
<td>Outside Japan</td>
<td>10,787</td>
<td>17,858</td>
</tr>
</tbody>
</table>

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1. Line items are based on IFRS.
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8. Number of employees at 167 companies including Otsuka Holdings Co., Ltd. and its subsidiaries (as of December 31, 2019).
Corporate Information, Global Network

Otsuka Holdings Co., Ltd.

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
104 (Consolidated: 32,992)

Business Description
Control, management and related activities with respect to the Company’s subsidiaries and affiliates operating in pharmaceutical, nutraceutical, consumer product, and other businesses.

Organizational Structure

Corporate Group

Overview

The Otsuka group of companies, whose origins date back to 1921, aims to contribute to the health of people around the world. It aims to do so through two main pillars: the pharmaceutical business for the diagnosis and treatment of diseases and the nutraceutical business to support the maintenance and promotion of everyday health. The company’s culture, summarized in a few words as “Ryukan-godo” (by sweat we recognize the way), “Jissho” (actualization) and “Shusse” (strategy), have been fostered by successive Otsuka leaders. These are amplified by our 47,000+ employees across 195 group companies in 31 countries and regions who strive to create and market unique products and services.

Global Network

As of December 31, 2019

Otsuka operates in
31 countries/regions

Otsuka Group Corporate Philosophy

Otsuka—people creating new products for better health worldwide

Overview

Under the corporate philosophy “Otsuka—people creating new products for better health worldwide,” Otsuka Pharmaceutical operates in two core businesses: the Pharmaceutical Business, which provides breakthrough treatments for patients around the world, and the Nutraceutical Business, which supports the maintenance and promotion of everyday health.

Organizational Structure

Otsuka Pharmaceutical Co., Ltd.

A total healthcare company supporting well-being for the whole body, from the treatment of diseases to the promotion of everyday health

Original company of the Otsuka group, and a leader in IV solutions in Japan with more than 70 years of experience in the field

Based on its management vision of being “The Best Partner in Clinical Nutrition,” Otsuka Pharmaceutical creates innovative products that meet a variety of needs, including pharmaceuticals, medical devices, oral rehydration solutions and other medical foods, and OTC pharmaceuticals. The company operates globally, with a focus on Japan and the rest of Asia.

Otsuka Pharmaceutical Factory, Inc.

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

Based on its management vision of being “The Best Partner in Clinical Nutrition,” Otsuka Pharmaceutical creates innovative products that meet a variety of needs, including pharmaceuticals, medical devices, oral rehydration solutions and other medical foods, and OTC pharmaceuticals. The company operates globally, with a focus on Japan and the rest of Asia.

Otsuka Warehouse Co., Ltd.

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

Since its founding, Otsuka Warehouse has operated businesses with an emphasis on pharmaceutical and food/food products logistics. This includes building a common distribution platform for the Otsuka group’s three core categories: pharmaceuticals, foods and beverages, and daily necessities. In recent years, Otsuka Warehouse has been working to extend its logistics solutions to outside the group.

Otsuka Chemical Co., Ltd.

Creatively giving shape to the power of materials for the future, together with customers

With materials at the core of its operations, Otsuka Chemical aims for continuous technological innovation that leads to the creation of products that enable higher standards of living. Otsuka Chemical provides products to global markets in automotive, electrical and electronic equipment, housing, healthcare areas through its main segments of the hydrazine business, the inorganic and composite materials business, and the pharmaceutical intermediates and active pharmaceutical ingredients (API) business.

Otsuka Foods Co., Ltd.

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

Otsuka Foods operates under the motto: “The company begins with people and food begins with spirit,” with “deliciousness, safety, peace of mind, and better health.” In the heart of the “spirit of food” shared by all employees, today, the aging of societies is among the many issues relating to food, the environment and demographic change that are transforming the social landscape. Otsuka Foods will continue to pursue solutions that address this kind of social change by meeting and providing the products that customers need, and be a company that contributes to people of the world.

Otsuka Medical Devices Co., Ltd.

Introducing new technologies that make Otsuka’s medical devices business unique

Otsuka Medical Devices seeks to grow the medical devices business, which operates mainly in Japan, China, and other Asian countries, into a core business for the Otsuka group. Otsuka Medical Devices is achieving further growth by bringing together the group’s experience and knowhow in medical devices in order to integrate the latest technology into new devices that meet emerging healthcare needs.

Europe
39 companies

Asia
68 companies

Oceania
3 companies

Middle East
2 companies

North America
33 companies

South and Central America
2 companies

Latin America
50 companies

Otsuka operates in
31 countries/regions
Disclosure of the Otsuka Group

The Otsuka group provides an overview of financial and non-financial information through this integrated report. Visit the Otsuka Holdings website for additional information, including consolidated financial statements, financial results presentations and supplementary documents, and information about research and development.

Website
https://www.otsuka.com/en/

Investor Relations

The Otsuka group CSR

Shareholder Information
(As of December 31, 2019)

Number of shares authorized 1,600,000,000 shares
Number of shares issued 557,835,617 shares
Number of shareholders 62,219

Stock Distribution
Treasury shares 2.75%
Other corporations 17.25%
Individuals and others 19.91%
Overseas corporations 21.88%
Securities companies 2.94%
Financial institutions 35.23%

Maximum/Minimum Stock Price and Volatility by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Maximum</th>
<th>Minimum</th>
<th>Volatility (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010/12</td>
<td>5,072</td>
<td>3,434</td>
<td>27.61%</td>
</tr>
<tr>
<td>2011/12</td>
<td>5,513</td>
<td>3,468</td>
<td>61.99%</td>
</tr>
<tr>
<td>2012/12</td>
<td>4,784</td>
<td>3,433</td>
<td>20.22%</td>
</tr>
<tr>
<td>2013/12</td>
<td>4,079</td>
<td>2,773</td>
<td>29.07%</td>
</tr>
<tr>
<td>2014/12</td>
<td>3,690</td>
<td>2,454</td>
<td>27.09%</td>
</tr>
<tr>
<td>2015/12</td>
<td>2,512</td>
<td>2,100</td>
<td>19.89%</td>
</tr>
<tr>
<td>2016/12</td>
<td>2,352</td>
<td>1,732</td>
<td>33.73%</td>
</tr>
</tbody>
</table>

Principal Shareholders (Top 10)

<table>
<thead>
<tr>
<th>Name of shareholder</th>
<th>Number of shares held (thousand)</th>
<th>Shareholding ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Nomura Trust and Banking Co., Ltd.</td>
<td>57,815</td>
<td>10.66</td>
</tr>
<tr>
<td>The Master Trust Bank of Japan, Ltd.</td>
<td>40,246</td>
<td>7.42</td>
</tr>
<tr>
<td>Otsuka Estate Co., Ltd.</td>
<td>25,296</td>
<td>4.29</td>
</tr>
<tr>
<td>Japan Trustee Services Bank, Ltd.</td>
<td>22,991</td>
<td>4.23</td>
</tr>
<tr>
<td>Otsuka Group Employee Shareholding Fund</td>
<td>12,998</td>
<td>2.39</td>
</tr>
<tr>
<td>The Asia Bank, Ltd.</td>
<td>10,970</td>
<td>2.02</td>
</tr>
<tr>
<td>Japan Trustee Services Bank, Ltd. (trust account 5)</td>
<td>7,728</td>
<td>1.42</td>
</tr>
<tr>
<td>Otsuka Asset Co., Ltd.</td>
<td>7,380</td>
<td>1.36</td>
</tr>
<tr>
<td>Japan Trustee Services Bank, Ltd. (trust account 8)</td>
<td>6,920</td>
<td>1.27</td>
</tr>
<tr>
<td>J.P. MORGAN CHASE BANK, 35-151</td>
<td>6,755</td>
<td>1.24</td>
</tr>
</tbody>
</table>

Total Shareholders’ Return

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Comparison (TOPIX Total Return Index)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015/12</td>
<td>122.1</td>
</tr>
<tr>
<td>2016/12</td>
<td>146.3</td>
</tr>
<tr>
<td>2017/12</td>
<td>145.1</td>
</tr>
<tr>
<td>2018/12</td>
<td>135.3</td>
</tr>
<tr>
<td>2019/12</td>
<td>148.8</td>
</tr>
</tbody>
</table>

Stock Performance

<table>
<thead>
<tr>
<th>Year</th>
<th>Stock price (¥)</th>
<th>Trading volume (right)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010/12</td>
<td>120,000</td>
<td>20,000</td>
</tr>
<tr>
<td>2011/12</td>
<td>90,000</td>
<td>15,000</td>
</tr>
<tr>
<td>2012/12</td>
<td>60,000</td>
<td>10,000</td>
</tr>
<tr>
<td>2013/12</td>
<td>30,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>
Significance of the Corporate Symbol

A symbolic representation of the 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 Os, the Otsuka name is spelled out in an open and friendly typeface. The corporate symbol conveys the Otsuka group’s energetic commitment to human happiness through good health.