



How We Will Grow Further Advancing as a Unique Total Healthcare Company

The Otsuka group's operations encompass two core businesses: the Pharmaceutical Business, which provides comprehensive health support from diagnosis to treatment of diseases, and the Nutraceutical Business, which contributes to maintaining and improving the health of healthy people. Going beyond the boundaries of a conventional pharmaceutical company, we aim to be an indispensable contributor to people's health worldwide, leveraging our strengths as a unique total healthcare company.

Business Strategy: Existing Business Value Maximization and New Value Creation

- Strengthen strategic initiatives for growth drivers four Global Products in the Pharmaceutical Business; three Major Brands and three Nurture Brands in the Nutraceutical Business
- Launch and nurture new drivers for sustainable growth in Pharmaceutical and Nutraceutical Businesses

Performance Target: Business Profit CAGR of 10% or More

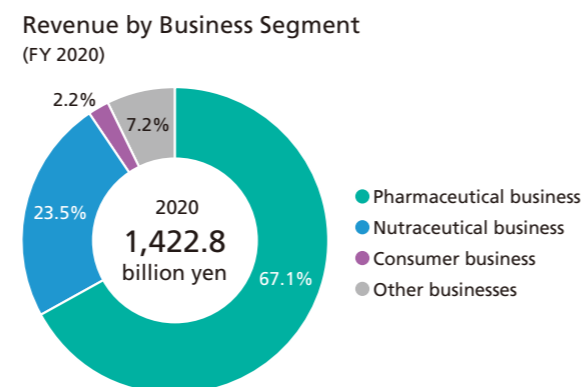
- Organic growth of mainstay products and brands in Pharmaceutical and Nutraceutical Businesses
- Actively invest in R&D to continue creating new drugs that will drive revenue during and beyond the next medium-term management plan

| | |
|---|---|
| Third Medium-Term Management Plan Targets (FY 2023) | Revenue: ¥1,700 billion |
| | Business profit: ¥200 billion (CAGR of 10% or more) |
| | ROE: 8.0% or higher |

Progress of the Third Medium-Term Management Plan

Overview of Fiscal 2020

In fiscal 2020, the second year of the Third Medium-Term Management Plan, though the COVID-19 pandemic had a certain impact, we took heightened health awareness as a growth opportunity. By leveraging our true value as a unique total healthcare company, we achieved revenue of 1,422.8 billion yen, an increase of 1.9% from the previous year, maintaining solid growth. Furthermore, business profit was 216.9 billion yen, an increase of 15.9% from the previous year, setting a record high since our stock listing.



| | Progress to date | | Third Medium-Term Management Plan: announcement as of May 2019 | | |
|-------------------------------------|------------------|---------|--|----------------|----------------|
| | 2019A | 2020A | 2021E | 2023E | CAGR 2018-2023 |
| (¥ billion) | | | | | |
| Revenue | 1,396.2 | 1,422.8 | 1,500.0 | 1,700.0 | 5.6% |
| Business profit before R&D expenses | 403.0 | 433.7 | 390.0 | 460.0 | 7.9% |
| R&D expenses | 215.8 | 216.8 | 230.0 | 260.0 | 6.1% |
| Business profit | 187.2 | 216.9 | 160.0 | 200.0 | 10.6% |
| ROE | 7.3% | 8.2% | 6.0% or higher | 8.0% or higher | — |

For more details about our *health*-related initiatives, visit:
<https://www.otsuka.com/en/csr/society/health/>



Among the Otsuka group's materialities, we set specific goals on the three health-related social issues (unmet medical and health needs, spread of infectious diseases, and nutritional needs) under the Third Medium-Term Management Plan (ending in fiscal 2023), and measures are being taken toward their resolution.

Social Issue 1: Unmet Medical and Health Needs

| Our Goal: Contribute to the resolution of unmet needs | |
|---|--|
| FY 2023 Goals | FY 2020 Progress |
| <ul style="list-style-type: none"> • Promotion of R&D for unmet needs <ul style="list-style-type: none"> Address unmet needs in the psychiatry and neurology areas Create first-in-class products in the oncology area Create first-in-class products in the cardiovascular and renal area • In areas with unmet needs <ul style="list-style-type: none"> New development projects: 10 or more Late-phase development projects advancing to the next phase: 30 or more | <ul style="list-style-type: none"> • In areas with unmet needs¹ <ul style="list-style-type: none"> New development projects: 9 projects² Late-phase development projects: 9 projects² |

1. Unmet needs areas defined by Otsuka based on *PatientsMap2020JP* and *PatientsMap2020US*, M3 & SSRI
2. Cumulative total since 2019

Social Issue 2: Spread of infectious Diseases

| Our Goal: Eradication of Tuberculosis | |
|--|--|
| FY 2023 Goals | FY 2020 Progress |
| <ul style="list-style-type: none"> • Provide <i>DELTYBA</i> (generic name: delamanid) for more than 60,000 cases • Supply <i>DELTYBA</i> for pediatric patients • Launch a clinical trial for new treatment regimen • Increase access to <i>DELTYBA</i> by collaborating with partners | <ul style="list-style-type: none"> • <i>DELTYBA</i> <ul style="list-style-type: none"> Provided <i>DELTYBA</i> for 40,000 cases in more than 110 countries/regions Acquired the indication of <i>DELTYBA</i> for children in Europe in October 2020 R-pharm acquired marketing approval for <i>DELTYBA</i> in Russia in May 2020 Implemented supply through the Global Drug Facility (GDF) of the Stop TB Partnership and alliance partners • Participated in Pan-TB collaboration and accelerated the development of new TB treatment regimen • Continued participation in the Global Health Innovative Technology Fund (GHIT Fund) |

Social Issue 3: Nutritional needs

| Our Goal: Creation of a System for the Realization of a Healthful Life | |
|--|--|
| FY 2023 Goals | FY 2020 Progress |
| <ul style="list-style-type: none"> • Challenge new categories and new areas • Create new systems and reinforce existing systems for realizing healthy lifestyles • Create new concepts and products keeping an eye on changes in environments | <ul style="list-style-type: none"> • Further increased the supply of plant-based food products by starting operations at a new manufacturing site • Executed cooperation agreements with all 47 prefectures in Japan promoted collaboration in health and other fields • Continued to hold the Women's Health Seminars • 30th anniversary of the Otsuka Health Comic Library • Cumulative total OATHAS registrants: Approximately 20,000 • Launched the Kenko Shacho ("Healthy President") service |

Pharmaceutical Business

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 four Global Products—*ABILIFY MAINTENA*, *REXULTI*, *Samsca/JINARC/JYNARQUE* and *LONSURF*—as growth drivers. We will further accelerate growth, targeting an increase in revenue by fiscal 2023 of 200 billion yen from Global Products, as well as 90 billion yen from New Products scheduled to be launched during the current Medium-Term Management Plan.

The Otsuka group focuses on unmet medical and health needs as a social issue. To this end, in fiscal 2020, we began eight new development projects to the next phase in the unmet needs areas (nine projects since fiscal 2019), and advanced three late-phase development projects to the next phase (nine projects since fiscal 2019), in unmet needs areas.*

* Unmet needs areas defined by Otsuka based on *PatientsMap2020JP* and *PatientsMap2020US*, M3 & SSRI

| (¥ billion) | FY 2020 revenue | Year-on-year | FY 2021 revenue plan | Growth rate |
|-------------------------------|-----------------|---------------|----------------------|--------------|
| <i>ABILIFY MAINTENA</i> | 116.0 | +14.0% | 128.0 | +10.3% |
| <i>REXULTI</i> | 104.6 | +16.5% | 110.5 | +5.6% |
| <i>Samsca/JINARC/JYNARQUE</i> | 168.3 | +12.9% | 170.5 | +1.3% |
| <i>LONSURF</i> | 40.7 | +18.1% | 43.5 | +6.8% |
| Total | 429.7 | +14.5% | 452.5 | +5.3% |

ABILIFY MAINTENA

aripiprazole | 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 and Japanese approval in 2020 for an additional indication for the treatment of bipolar disorder, prescriptions are increasing.

REXULTI

brexpiprazole | Atypical antipsychotic

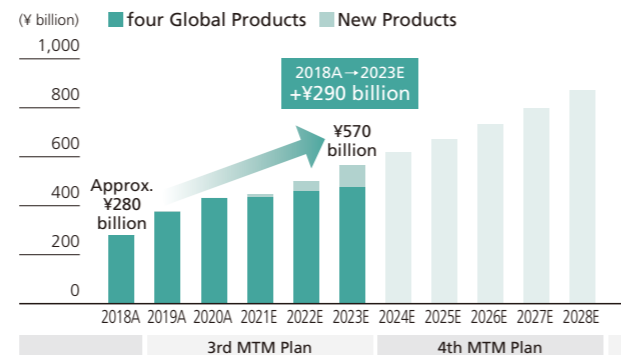
Marketed as an adjuvant treatment for major depressive disorder and as a treatment for schizophrenia in the U.S., this drug is highly evaluated for its efficacy and safety as a new treatment option for both diseases. In Japan, where the drug is marketed as a treatment for schizophrenia, prescriptions have grown significantly. 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.

Progress of four Global Products

For the four Global Products, we expanded regions and added indications overseas, and worked to increase awareness of convenient dosage formulations of our drugs. Revenue in fiscal 2020 rose 14.5% from the previous year, making a considerable contribution to growth in consolidated performance.

Revenue Plan for the four Global Products and New Products

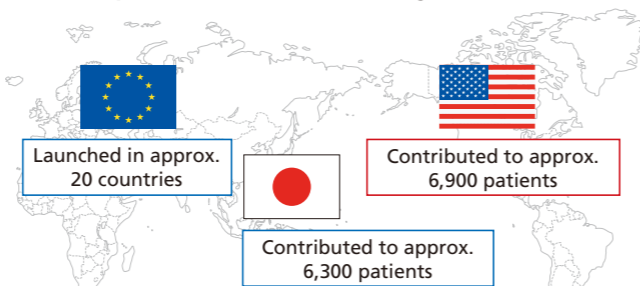


Samsca/JINARC/JYNARQUE

tolvaptan | V₂-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 autosomal dominant polycystic kidney disease (ADPKD), an intractable renal disease, are increasing owing to the promotion of proper use guidelines and disease awareness activities. The drug has also

Global operation as an ADPKD drug



Estimated number of ADPKD patients
 U.S.: 140,000, Europe: 205,000, Japan: 31,000
 (As of March 31, 2021, in-house survey)

contributed to the resolving of unmet needs following approval for the additional of indicational for the syndrome of inappropriate antidiuretic hormone secretion (SIADH) in June 2020.

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, leading to a steady increase in prescriptions. In Europe also, *JINARC* is sold in approximately 20 countries and the number of patients receiving treatment through the drug is on the increase.

LONSURF

trifluridine/tipiracil | Anticancer agent

Backed by strengthened information provision as a treatment option for unresectable advanced or recurrent colorectal cancer, and approval for the additional indication of unresectable advanced or recurrent gastric cancer in Japan, the U.S. and Europe, prescriptions for *LONSURF* have been increasing. In the U.S. in particular, where home treatment and the use of oral anticancer agent are recommended given the COVID-19 pandemic, and *LONSURF* is being selected as one such oral therapy. To further maximize its value, we are currently pursuing promotion to lines of therapy and clinical studies for treatment combinations.



Timothy Whitten
 Taiho Oncology, Inc.
 President and CEO

Growing the North American Oncology Business

In 2020, Taiho Oncology had a strong year despite the COVID-19 pandemic. *LONSURF* sales grew significantly in metastatic colorectal cancer (mCRC) and metastatic gastric cancer, and the pandemic helped reveal the value of oral therapies as treatment options for cancer patients. Also, Taiho Oncology launched *INQOVI* into the market for myelodysplastic syndromes and is now a multi-product commercial organization focused on both solid and liquid tumors.

For the remainder of the medium-term plan, we are planning for continued growth in North America based on the following: potential *LONSURF* growth through a clinical trial life-cycle management plan studying *LONSURF* in treatment combinations and earlier in the course of mCRC; completing initial *INQOVI* launch; potentially commercializing new compounds originating from in-house discovery programs; and aggressively looking for external near-to-market in-licensing opportunities.

Additionally, our development organization continues to plan and implement clinical trials focused on exciting compounds originating from the Tsukuba Research Center.

DELTYBA

The Otsuka group considers the spread of infectious diseases as a social issue, and targets the eradication of tuberculosis (TB), one of the infectious diseases with the largest death toll in the present day. More than ten million people develop TB and approx. 1.5 million die of TB annually. As the culmination of more than 30 years of R&D, the Otsuka group developed *DELTYBA*, one of the world's first new TB drugs in about half a century. As of December 2020, it is available in more than 110 countries/regions as an important option for patients with multidrug-resistant TB. In October 2020, it was approved for an additional pediatric indication in Europe. Eradicating tuberculosis is still a major challenge worldwide. In support of that effort, Otsuka has been working to expand access to *DELTYBA*, and since 2016 has shipped enough doses to treat more than 40,000 cases.

- ▶ Supply from Stop TB Partnership's GDF (since February 2016)
- ▶ Participation in access programs implemented by countries and public international organizations
 - endTB program conducted by United (a global health agency)
 - Access programs implemented by the governments of South Africa and India
- ▶ Access through alliance partners
 - Alliance with R-Pharm JSC (Russia, CIS, etc.)
 - Alliance with Mylan N.V. (now Viatrix Inc.) (India, South Africa, and other high-burden countries)
- ▶ Access through the compassionate use program¹
 - Supplied to more than 200 patients in 19 countries²

1. Public programs that provides exceptional access to yet-to-be-approved drugs on an exceptional basis to patients with serious or life-threatening diseases
 2. Ghosh S et al., *Eur Respir J.* 2020 Nov 26; 2002483.

For more details about our TB initiatives, visit:
<https://www.otsuka.com/en/csr/society/health/pharmaceutical.html>



Future of Pharmaceutical Business

Opportunities and Risks

Risks that affect the environment surrounding the Pharmaceutical Business operating include those relating to reduced visits to medical institutions and delayed clinical development due to the global the COVID-19 pandemic, intensifying competition, paradigm shifts in treatment due to technological innovation, and policies

implemented in response to medical cost inflation, which has become a serious issue worldwide. Despite these risks, the Otsuka group is developing its multiple pipelines in multiple areas in order to contribute to the resolution of social issues, through initiatives targeting with diseases with high unmet needs.

| | |
|--|---|
| <p>Strengths</p> <ul style="list-style-type: none"> • 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 • Stable profit in the IV solutions business • Originality free from fixed ideas <p>Opportunities</p> <ul style="list-style-type: none"> • Advances in science and technology, and the progress of basic research related to diseases • Creation of synergies in therapeutic drugs through advances in digital technologies • Promotion of precision medicines to enhance efficacy | <p>Weaknesses</p> <ul style="list-style-type: none"> • Management personnel with advanced skills for diversifying businesses • Strengthening portfolio management related to patent expiration for mainstay products <p>Threats</p> <ul style="list-style-type: none"> • 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 • Pandemic related to the spread of infectious diseases |
|--|---|

Future initiatives

In the Pharmaceutical Business, we are promoting various measures toward the resolution of issues. We are taking on challenges in new areas that only Otsuka can do, resolving unmet needs, and generating innovations based on creative and diverse research platforms.

With a focus on the psychiatry and neurology, oncology, and cardiovascular and renal areas –, where satisfaction with current treatment methods for many diseases remains with low –, we aim to create innovative new drugs through unique approaches that leverage the synergy of our diverse businesses.

● 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, there are concerns about the increase in Alzheimer's disease as the world population ages. 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.

We have a high-potential pipeline and product lineup, and aim to become a top-class global player in this area.

Agitation Associated with Dementia of the Alzheimer's Type

It is estimated that approximately 3.76 million people (estimated 2021)* 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 drugs with different mechanisms of action, brexpiprazole (REXULTI) and AVP-786.

We hope that these therapeutic development projects will contribute not only to the physical well-being of patients, but also to the mental well-being and social well-being including caregivers, and will become a solution for the realization of a sustainable society.

* ©2021 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited.

Status of Psychiatry and Neurology Pipelines

(As of March 31, 2021)

| Pipeline | Features | Indication | Country/Region | Development status | |
|---------------------------------------|---|--|-------------------|--------------------|---|
| brexpiprazole | Dopamine partial agonist | Major depressive disorder | Japan/Europe | Phase III | |
| | | Schizophrenia | China | Phase III | |
| | | Agitation associated with dementia of the Alzheimer's type | Japan/U.S./Europe | Phase III | |
| | | Post-traumatic stress disorder | U.S. | Phase III | |
| | | Borderline personality disorder | U.S. | Phase II | |
| | | Schizophrenia; long-acting injectable | U.S. | Phase I | |
| aripiprazole (long-acting injectable) | Dopamine partial agonist | Bipolar disorder | Japan | Approved* | ● |
| | | Schizophrenia | China | Filed | ● |
| OPC-64005 | Serotonin, norepinephrine and dopamine reuptake inhibitor | Major depressive disorder | Japan | Phase II | ● |
| AVP-786 | NMDA receptor antagonist; serotonin and norepinephrine reuptake inhibitor; sigma-1 receptor agonist | Agitation associated with dementia of the Alzheimer's type | U.S./Europe | Phase III | |
| | | Negative symptoms of schizophrenia | U.S. | Phase II/III | |
| | | Traumatic brain injury | U.S. | Phase II | |
| | | Intermittent explosive disorder | U.S. | Phase II | |
| centanafadine | Norepinephrine, dopamine and serotonin reuptake inhibitor | Attention deficit hyperactivity disorder | U.S. | Phase III | |
| pizuglanstat | PGD synthase inhibitor | Duchenne muscular dystrophy | Japan | Phase III | ● |
| fremanezumab | Anti-CGRP antibody | Migraine | Japan | Filed | ● |
| OPC-214870 | — | Epilepsy | U.S. | Phase I | |

■ Development projects in unmet needs areas as defined by Otsuka based on *PatientsMap2020JP* and *PatientsMap2020US*, M3 & SSRI

● Project that has advanced in or after fiscal 2020

* Approved September 2020, brand name ABILIFY prolonged release aqueous suspension for IM injection

● Oncology

Maximizing business value through proprietary drug discovery platforms and initiatives for new drug discovery technologies and methodologies

Taiho Pharmaceutical has a broad portfolio supported by its proprietary drug discovery platform technologies, including proprietary biochemical modulation technology uniquely developed its history, as well as the Cysteinomix drug discovery technology¹ enabling specific covalent modification of therapeutic targets, and fragment-based drug discovery technology² established by Astex Pharmaceuticals. The company is also accelerating development of drugs to resolve unmet needs, working with pharmaceutical collaborators. Furthermore, it looks for opportunities for collaboration with promising startups through corporate venture capitals, thereby expanding its development pipelines in cancer immunotherapy and other areas, and acquiring innovative drug discovery platform technologies.

Meanwhile, centering on external collaborations, Otsuka Pharmaceutical is taking on the challenge of establishing new therapies with a focus on the future. This includes creating synergies with new modalities, in areas such as gene-modified T cell therapies.

Individual group companies are combining their accumulated assets in their fields of their strengths to bolster global operations and enhance business value.

1. Platform for discovering compounds that cause specifically from a covalent bonding with reactive amino acid residues (mainly cysteine residues) of protein as potential drug target proteins
2. Technology to create new compounds through molecular design. It clarifies interactions between small-molecular fragments showing pharmacological activity that cannot be measured in high-throughput screening and large molecule proteins with complicated 3D structures that have been implicated in diseases and are potential drug targets.

● 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 alliances with Akebia Therapeutics for vadadustat and with Aurinia Pharmaceuticals for voclosporin, and the acquisition of Visterra, a company with a renal disease-related pipeline. Otsuka group also strive to find solutions to unmet needs which are not resolved by drugs. We are advancing development of

unique medical devices, drawing on our innovative technology and our strengths in drugs and clinical research. Ultrasound renal denervation treatment is a new therapy expected to decrease high blood pressure in cases that cannot be effectively treated with existing drugs, and our ultrasound renal denervation system has Breakthrough Device Designation from the U.S. FDA. We will aiming to create first-in-class products through new drug discovery technologies and medical devices.



Toshiki Sudo
Executive Director
(Research and Intellectual Property)
Otsuka Pharmaceutical

Strengths in Drug Discovery at Otsuka Pharmaceutical

Otsuka Pharmaceutical has a global satellite research structure with sites in Japan, the U.K., the U.S., and China, thereby pursuing drug discovery through diverse modalities including small-molecular drugs, antibodies, and cell & gene therapies. The company's small-molecular drug discovery platforms have created first-in-class drugs in the central nervous system, cardiovascular system, and renal areas. In addition, Astex in the U.K. has acquired approval for several new oncology drugs through fragment-based drug discovery based on the protein structural analysis and computational chemistry. Visterra in the U.S. is engaged in antibody drug discovery based on its proprietary antibody preparation technology. Otsuka Pharmaceutical aims to contribute to global healthcare by creating innovative drugs through open innovations with the academia and biotech in and outside Japan.

Status of Cardiovascular and Renal Pipelines

(As of March 31, 2021)

| Pipeline | Features | Indication | Country/Region | Development status | |
|-------------------------------------|--|--|-------------------|--------------------|---|
| tolvaptan | V ₂ -receptor antagonist | Syndrome of inappropriate antidiuretic hormone secretion | Japan | Approved* | ● |
| OPC-61815 | V ₂ -receptor antagonist | Cardiac edema | Japan | Filed | ● |
| vadadustat | HIF-prolyl hydroxylase inhibitor | Renal anemia | U.S. | Filed | ● |
| | | | Europe | Phase III | |
| VI5649 | Anti-APRIL monoclonal | IgA nephropathy | Japan/U.S./Europe | Phase II | ● |
| Ultrasound renal denervation system | Cauterization of renal sympathetic nerves (medical device) | High blood pressure | Japan/U.S./Europe | — | |

Development projects in unmet needs areas as defined by Otsuka based on *PatientsMap2020JP* and *PatientsMap2020US*, M3 & SSRI

● Project that has advanced in or after fiscal 2020

* Approved June 2020, brand name *Samsca*

Status of Oncology Pipelines

(As of March 31, 2021)

| Pipeline | Features | Indication | Country/Region | Development status | |
|------------------------|--|--|-------------------|--------------------|---|
| ASTX727 | DNA methyltransferase inhibitor | Myelodysplastic syndromes | U.S. | Approved* | ● |
| | | | Japan | Phase I | |
| | | Acute myeloid leukemia | Europe | Phase III | ● |
| tolinapant | IAP inhibitor | Solid tumors, lymphomas | U.S. | Phase II | |
| | | T-cell lymphoma | Japan | Phase I | |
| tolinapant + ASTX727 | IAP inhibitor+ DNA methyltransferase inhibitor | Acute myeloid leukemia | U.S. | Phase I | ● |
| ASTX029 | ERK1/2 inhibitor | Solid tumors | U.S. | Phase I/II | |
| ASTX295 | MDM2 inhibitor | Solid tumors | U.S. | Phase I/II | |
| ASTX030 | DNA methyltransferase inhibitor | Myelodysplastic syndromes | Japan/U.S. | Phase I | ● |
| ponatinib | BCR-ABL tyrosine kinase inhibitor | Chronic myeloid leukemia, acute lymphoblastic leukemia | China | Phase II | ● |
| OPB-111077 | — | Diffuse large B-cell lymphoma | Japan | Phase I | |
| | | Hematological cancers | U.S. | Phase I | |
| OPB-171775 | — | Solid tumors | Japan | Phase I | ● |
| TAS-114 | dUTPase inhibitor | Non-small cell lung cancer | Japan/U.S./Europe | Phase II | |
| pamufetinib | Multi-kinase inhibitor | Osteosarcoma | Japan | Phase III | ● |
| | | Prostate cancer | Japan | Phase II | |
| pimitespib | HSP90 inhibitor | Gastrointestinal stromal tumor | Japan | Phase III | |
| | | Solid tumors | U.S./Europe | Phase I | |
| TAS-117 | — | Solid tumors | Japan | Phase I | |
| futibatinib | FGFR inhibitor | Cholangiocarcinoma | Japan/U.S./Europe | Phase III | ● |
| | | Breast cancer | U.S./Europe | Phase II | ● |
| | | FGFR aberrations cancers | Japan/U.S./Europe | Phase II | ● |
| | | Urothelial cancer | U.S./Europe | Phase II | ● |
| TAS0313 | Peptide vaccine | Urothelial cancer | Japan | Phase II | |
| TAS3681 | — | Prostate cancer | U.S./Europe | Phase I | |
| TAS0728 | — | Solid tumors | U.S./Europe | Phase I/II | |
| TAS0612 | — | Solid tumors | U.S./Europe | Phase I | ● |
| TAS1440 | LSD1 inhibitor | Acute myeloid leukemia | U.S. | Phase I | ● |
| TAS0953 | — | Solid tumors | Japan | Phase I/II | ● |
| TAS1553 | — | Acute myeloid leukemia | U.S. | Phase I | ● |
| trabectedin (YONDELIS) | — | Ovarian cancer | Japan | Phase I | |
| canerpatrev | Oncolytic virus | Pancreatic cancer | Japan | Phase I | |
| TBI-1301 | NY-ESO-1 siTCR™ gene therapies | Synovial sarcoma | Japan | Phase I/II | |
| TBI-1501 | CD19 CAR gene therapies | Acute lymphoblastic leukemia | Japan | Phase I/II | |
| fosnetupitant | NK ₁ receptor antagonist | Chemotherapy-induced nausea and vomiting | Japan | Filed | ● |

Development projects in unmet needs areas as defined by Otsuka based on *PatientsMap2020JP* and *PatientsMap2020US*, M3 & SSRI

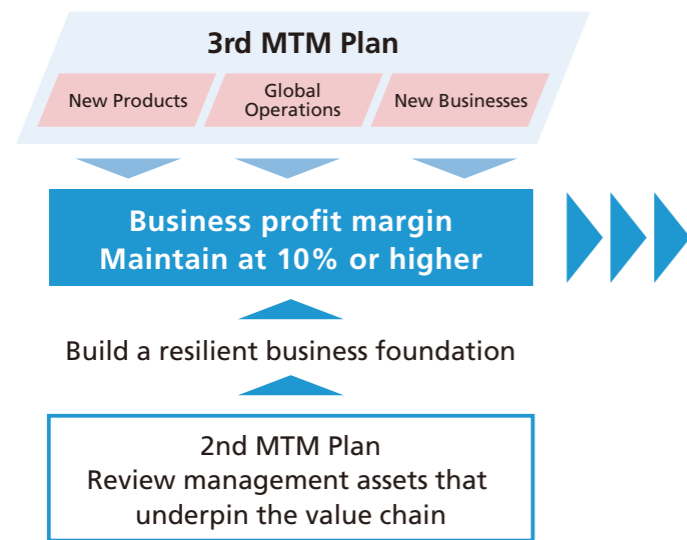
● Project that has advanced in or after fiscal 2020

* Approved July 2020, brand name *INQOVI*

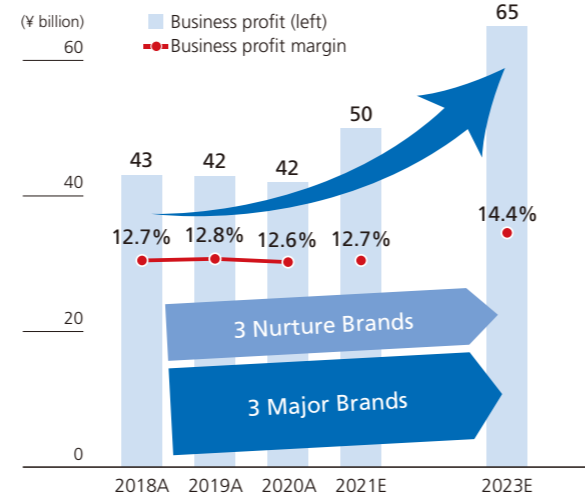
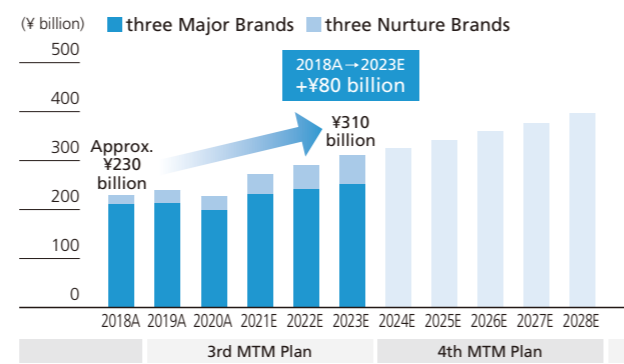
Nutraceutical Business

The Third Medium-Term Management Plan calls for revenue growth of 40 billion yen in the three Major Brands—*POCARI SWEAT*, *Nature Made*, and *N&S*—and 40 billion yen in the three Nurture Brands—*BODYMAINTÉ*, *EQUELLE* and *Daiya*.

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.



Revenue Plan for three Major Brands and three Nurture Brands



Progress of three Major Brands

POCARI SWEAT

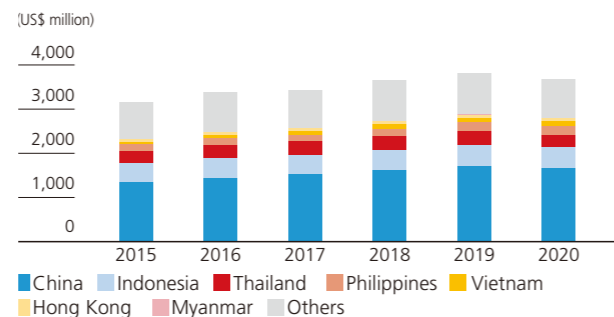
Overseas, mainly in Asia, sales volume for *POCARI SWEAT*, a beverage for replenishing fluids and electrolytes, is increasing due to awareness activities tailored to the characteristics and needs of each region. The CAGR* of the Asia-Pacific sports beverage market (excluding Japan) was 2.1% for the period 2016 to 2020. 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.

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.

*Euromonitor International of the U.K.

Sports Beverage Market (Asia-Pacific*)



Euromonitor International of the U.K. * Excluding Japan

POCARI SWEAT
overseas revenue plan
CAGR
(2018–2023)
9.4%

ION SUPPLY DRINK
POCARI SWEAT

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 Pharmacopeia (USP), *Nature Made* is a leading choice of U.S. pharmacists.

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



* Euromonitor International of the U.K.

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” foods¹ and alternative products are attracting the attention of the millennial generation and others. In fiscal 2020, 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 12.3%, while the gluten-free food market was worth around 2.1



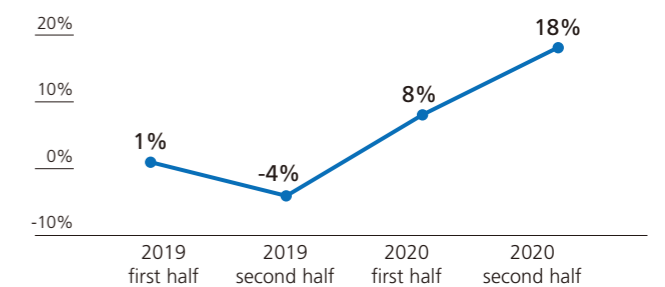
billion U.S. dollars after expanding at a CAGR of 12.3%².

N&S, a health and nutritional food company, provides



1. Based on total U.S. retail sales aggregate data reported through the Scantrack service in the supplement vitamin category for the 52-week period ended December 27, 2020. ©2020 Information Resources Inc.
2. INTAGE SRI Health Food Multivitamin Market, cumulative market share by brand for January–December 2020
3. US News & World Report and Pharmacy Times 2020 Survey: Product categories: Letter Vitamins (A–E), Coenzyme Q10, Omega-3/Fish Oil, Flax Seed Oil, Herbal Supplements, Mood Health Supplements, Diabetic Multivitamins, Cholesterol Management—Natural, Garlic Supplements

YoY Change in *Nature Made* Revenue



health foods and other products in more than 40 countries around the world, centered on Europe. At each of its manufacturing sites, N&S has obtained ISO 14000 and ISO 12000, as well as IFS certification, an international standard for auditing food manufacturers, and conducts production with concern for the environment and a high level of quality management. In 2017, N&S built a new factory for gluten-free products in France and strengthened the development of free-from products to meet evolving consumer needs.

1. Food products free from specific ingredients; foods that do not contain gluten are referred to as gluten-free products
2. Euromonitor International of the U.K. (Retail Value RSP)



Jeff Boutelle
CEO, Pharmavite LLC

Pharmavite Transformation Continues in 50th Anniversary Year

At Pharmavite, we’re continuing to build for the future and we’re ahead of our Medium-Term Management Plan as our transformation accelerates. We are shifting toward new ways in business model and mindset, while staying true to our foundational values rooted in science and quality. That means our business model is transitioning from a historically retail-focused company to further leveraging science. This is a unique moment where consumers are focused on proactive maintenance of their health and wellness. Pharmavite is seeking to meet that need by leveraging science, technology and innovation as a leader in preventative solutions. On the occasion of Pharmavite’s 50th anniversary, we reflect back on our founders’ philosophy of nutrition as the basis for proactive maintenance of health and wellness, while focusing on our future of bringing the gift of health to life with our *Nature Made*, *MegaFood*, *EQUELLE* and *Nurish* by *Nature Made* brands.

Progress of three Nurture Brands

BODYMAINTÉ

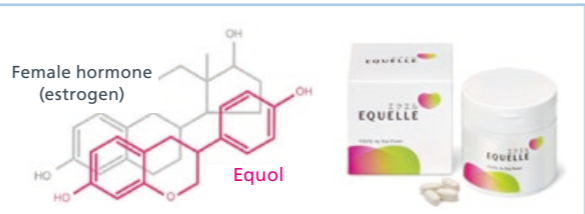
BODYMAINTÉ was commercialized based on research conducted by Otsuka Pharmaceutical on the themes of "intestines and nutrition" and "exercise and nutrition," and contains B240, a proprietary lactic acid bacteria. Focusing on health management for athletes exposed to risks related to intense training, we developed BODYMAINTÉ Jelly, a conditioning food that has won the support of many athletes and sports trainers. We also developed BODYMAINTÉ Drink, a conditioning beverage containing B240, to help replenish fluids and electrolytes that support proper hydration. BODYMAINTÉ Drink expands the value of this product line by supporting the health management of more consumers.



Plant-Derived Lactic Acid Bacteria B240
Lactobacillus pentosus ONRICb0240 is a plant-derived lactic acid bacteria isolated through the fermentation of a type of tea leaf, traditionally consumed in northern Thailand. It was isolated by Sanae Okada, Professor Emeritus of Tokyo University of Agriculture* and its efficacy was confirmed by Otsuka Pharmaceutical.
 *J Gen. Appl. Microbiol. 1986;32:57-65

EQUELLE

EQUELLE originated from research conducted at Otsuka Pharmaceuticals' Saga Nutraceuticals Research Institute, where women's health is a research theme. EQUELLE, 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. Otsuka Pharmaceutical provides a broad range of information concerning nutrition for women's health on its website and through other media.



Equol
 Equol is an ingredient produced when daidzein, a soybean isoflavone, is metabolized by intestinal bacteria. One aspect of Otsuka Pharmaceutical's many years of soybean research was a focus on the properties of equol. The Saga Nutraceuticals Research Institute succeeded in isolating the *Lactococcus* 20-92 strain, a lactic acid bacteria that produces equol. We publicize the progress results of a variety of research and continue to be a leader in global research in this field.

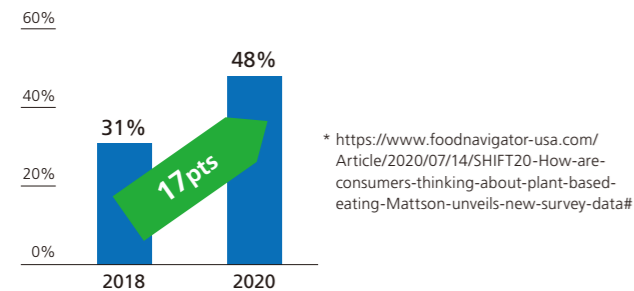
Daiya

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

The U.S. plant-based alternatives market continues to grow. Daiya Foods is expanding its sales channels and product lineup, mainly in the area of cheese alternatives, which are their core product. Under the Third Medium-Term Management Plan, we plan to achieve a revenue CAGR of 25%.



Percentage of People Who Bought Plant-Based Foods because of Environmental Concerns*



Future of Nutraceutical Business

Opportunities and Risks

The Nutraceutical Business involves risks such as stagnation in the global economy due to the COVID-19 pandemic, intensifying competition, a diminishing market in Japan due to population decline, and sluggish markets due to unseasonable weather. Despite these risks, we pursue the solutions to emerging health

issues. Utilizing expertise honed in its Pharmaceutical Business, the Otsuka group will develop original science-based products that support each person's aspirations to live a healthy life. We will continue to identify underlying health needs by examining social issues, and develop our business with a focus on functional beverages and functional food products that resolve those needs.

| | |
|---|--|
| <p>Strengths</p> <ul style="list-style-type: none"> • Creative products and marketing based on scientific evidence • POCARI SWEAT and other products with long-term popularity • Overseas businesses that incorporate solutions to social issues with their core business processes • Steady earnings power <p style="text-align: right; font-size: 2em; color: #0070C0;">Strength</p> | <p>Weaknesses</p> <ul style="list-style-type: none"> • Management personnel with advanced skills for diversifying businesses • Brand development in this field takes time <p style="text-align: right; font-size: 2em; color: #0070C0;">Weakness</p> |
| <p>Opportunities</p> <ul style="list-style-type: none"> • Rising consumer awareness of self-medication, prevention and daily health in tandem with medical cost inflation • Diversification of diet <p style="text-align: right; font-size: 2em; color: #0070C0;">Opportunity</p> | <p>Threats</p> <ul style="list-style-type: none"> • Sluggish overall beverage market due to unseasonal weather • Intensification of competition in core areas due to entry of new competitors • Pandemic related to the spread of infectious diseases <p style="text-align: right; font-size: 2em; color: #0070C0;">Threat</p> |

Future Initiatives

At our R&D site in Nutraceutical Business, we investigate themes such as nutrition and exercise from unique viewpoints that utilize expertise honed in our Pharmaceutical Business. Our

goal is to develop and provide the world with creative products that maintain and improve people's health, 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.



Otsu Skin Care Research Institute

Otsu Skin Care Research Institute performs R&D of cosmetics. We wanted to improve people's health not only from within, but also from without, by ensuring the skin, the body's protective covering, was cared for. Focusing on the ingredient AMP¹, a substance found naturally in the body, we developed Energy Signal AMP². Its active ingredient supports skin turnover and encourages melanin excretion from the body, and is contained in the main products of the *InnerSignal* series. *UL-OS* contains moisturizing ingredient AMP³, which is based on Otsuka's proprietary formula. The product line has steadily expanded to include moisturizer, sunblock, skin wash, refresh sheets, shampoo, and whitening care,⁴ and has grown into a brand that offers total skin care for the body from head to toe.

1. Adenosine monophosphate
2. Disodium Adenosine monophosphate OT
3. Adenosine monophosphate (moisturizing ingredient)
4. Suppresses production of melanin and prevents skin blemishes and freckles

InnerSignal



Creation of a System for the Realization of a Healthful Life

The Otsuka group focuses on nutritional needs as a social issue, and pursues the creation of a system for the realization of a healthful life.

Support for Health & Productivity Management

Otsuka Pharmaceutical launched Kenko Shacho ("Healthy President,") a community website through which management executives across Japan can network and access information and services that support health and productivity management. To further enhance services and membership, we have launched comprehensive measures for health promotion among people of working age in collaboration with local governments, associations, companies and other organizations.

Women's Health

Our experts in women's health carry out activities across Japan to spread accurate understanding of the mental and physical changes experienced by women and related health issues, as well as solution to those issues. We also provide broad information concerning nutrition for enhancing women's health on the Otsuka Pharmaceutical website. The OATHAS program for developing healthy aging supporters is targeted at pharmacists who provide health support to local communities, enabling participants to acquire not only knowledge but also practical skills required for health support.

Otsuka Health Comic Library

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 Japan 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 the medium of comics. Every year we choose a different theme and publish a new volume. The comics are donated to elementary schools, special needs schools, Japanese schools overseas, and public libraries.



Raising Awareness of Proper Hydration

Otsuka Pharmaceutical's website includes an information section titled Protect Yourself From Heat Disorders and a section presenting content based on the Japan Sport Association's *A Guidebook for the Prevention of Heat Disorder During Sports Activities (First Edition)*. Another initiative is the Heat Disorders Prevention website, which was created in collaboration with weather forecasters. Through these and other activities, we are further raising awareness of the topic. In addition, Otsuka Pharmaceutical Factory, which sells *OS-1*, an oral rehydration solution, provides operational support for Oshiete! "Kakure Dassui" linkai, an organization that raises awareness of ways to prevent and treat dehydration before it becomes critical.



Maintaining and Improving People's Day-to-Day Health

Our goal in the Nutraceutical Business is to support the maintenance and improvement of people's health worldwide, thereby contributing to longer healthy life expectancy. To this end, we address yet-to-emerge needs and social issues through unique concepts. With an eye on changes in the global landscape, we 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, while strengthening collaboration with external institutions.