

# Review of Current and Past Medium-Term Management Plans, and Looking Forward to the Next Medium-Term Management Plan

Click here for details of the 3rd Medium-Term Management Plan.

<https://www.otsuka.com/en/ir/management/plan.html>



Under the corporate philosophy of “Otsuka people creating new products for better health worldwide,” the Otsuka group aims to become an indispensable contributor to the people’s health worldwide as a total healthcare company. With the formulation of medium-term management plans, we will continue contributing to society and achieving sustainable growth through “what only Otsuka can do,” based on our DNA of *Ryukan-godo*, *Jisho*, and *Sozosei*.

## Review of past medium-term management plans

	The 1st Medium-Term Management Plan (FY 2011-FY 2013)	The 2nd Medium-Term Management Plan (FY 2014-FY 2018)	The 3rd Medium-Term Management Plan (FY 2019-FY 2023) <sup>1</sup>
<b>Gist of the Medium-Term Management Plan</b>	<b>Three years to establish a world-class structure as a global healthcare company with both medical and nutraceutical businesses</b>	<b>Establish a diversified earnings structure to achieve sustainable growth</b>	<b>Advance in the Global Market as a Unique Total Healthcare Company ~ Five-Year Growth Phase ~</b>
<b>Final year targets of the Medium-Term Management Plan</b>	<b>FY 2013 Plan (announced in May 2011)</b> <ul style="list-style-type: none"> <li>Revenue: ¥1,330 billion</li> <li>Research and development expenses: ¥200.0 billion</li> <li>Operating income: ¥200.0 billion</li> <li>Profit: ¥130.0 billion</li> <li>EPS: ¥230</li> <li>ROE: 10% or more</li> </ul>	<b>FY 2018 Plan (announced in August 2014)</b> <ul style="list-style-type: none"> <li>Revenue: ¥1,440.0 billion</li> <li>Operating income before investment in R&amp;D expenses: ¥370.0 billion</li> <li>Research and development expenses: ¥170.0 billion</li> <li>Operating income: ¥200 billion</li> <li>ROE: 8-10%</li> </ul>	<b>FY 2023 Plan (announced in May, 2019)</b> <ul style="list-style-type: none"> <li>Revenue: ¥1,700.0 billion</li> <li>Business profit before R&amp;D expenses: ¥460.0 billion</li> <li>Research and development expenses: ¥260.0 billion</li> <li>Business profit<sup>2</sup>: ¥200 billion (CAGR above 10%)</li> <li>ROE: 8.0% or more</li> </ul>
<b>Results</b>	<b>FY 2013 Results</b> <b>Revenue and profit grew faster than originally planned.</b> <ul style="list-style-type: none"> <li>Revenue: ¥1,452.8 billion</li> <li>Research and development expenses: ¥249.0 billion</li> <li>Operating income: ¥198.7 billion</li> <li>Profit: ¥151.0 billion</li> <li>EPS: ¥278.1</li> <li>ROE: 10.8%</li> </ul>	<b>FY 2018 Results</b> <b>Established a diversified revenue structure</b> <ul style="list-style-type: none"> <li>Revenue: ¥1,292.0 billion</li> <li>Operating income before investment in R&amp;D expenses: ¥324.4 billion</li> <li>Research and development expenses: ¥192.9 billion</li> <li>Operating income: ¥108.3 billion</li> <li>ROE: 4.7%</li> </ul>	<b>FY 2023 Results</b> <ul style="list-style-type: none"> <li>Revenue: ¥2,018.6 billion</li> <li>Business profit before R&amp;D expenses: ¥620.4 billion</li> <li>Research and development expenses: ¥307.8 billion</li> <li>Business profit: ¥312.6 billion</li> <li>ROE: 5.3%</li> </ul>
<b>Issues</b>	<b>Pharmaceutical Business</b> <ul style="list-style-type: none"> <li>Strengthening of core therapeutic areas</li> <li>Diversification of the sales structure</li> </ul> <b>Nutraceutical Business</b> <ul style="list-style-type: none"> <li>Revision of business assets that support the value-chain</li> <li>Acceleration of global expansion</li> <li>Improvement of profitability</li> </ul>	<b>Pharmaceutical Business</b> <ul style="list-style-type: none"> <li>Maximizing value of existing businesses</li> <li>Try new frontiers that only Otsuka can do</li> <li>Generate innovation from creative and diverse research platforms</li> </ul> <b>Nutraceutical Business</b> <ul style="list-style-type: none"> <li>Creating new concepts keeping an eye on changes in the environments</li> <li>Trying new categories and new areas</li> <li>Maintaining a high profit margin structure</li> </ul>	<b>Pharmaceutical Business</b> <ul style="list-style-type: none"> <li>Steadily executing trials of late-stage development projects, nurturing new products, further expanding the product pipeline that will drive growth beyond 2030, expanding business opportunities through collaboration, and increasing profitability by maximizing value of existing products</li> <li>Cultivating human resources who can create innovation</li> </ul> <b>Nutraceutical Business</b> <ul style="list-style-type: none"> <li>Further expanding the scope of business, particularly for Major Brands</li> <li>Accelerating growth of Nurture Brands that support future businesses</li> <li>Creating products based on new concepts and developing new markets</li> </ul>

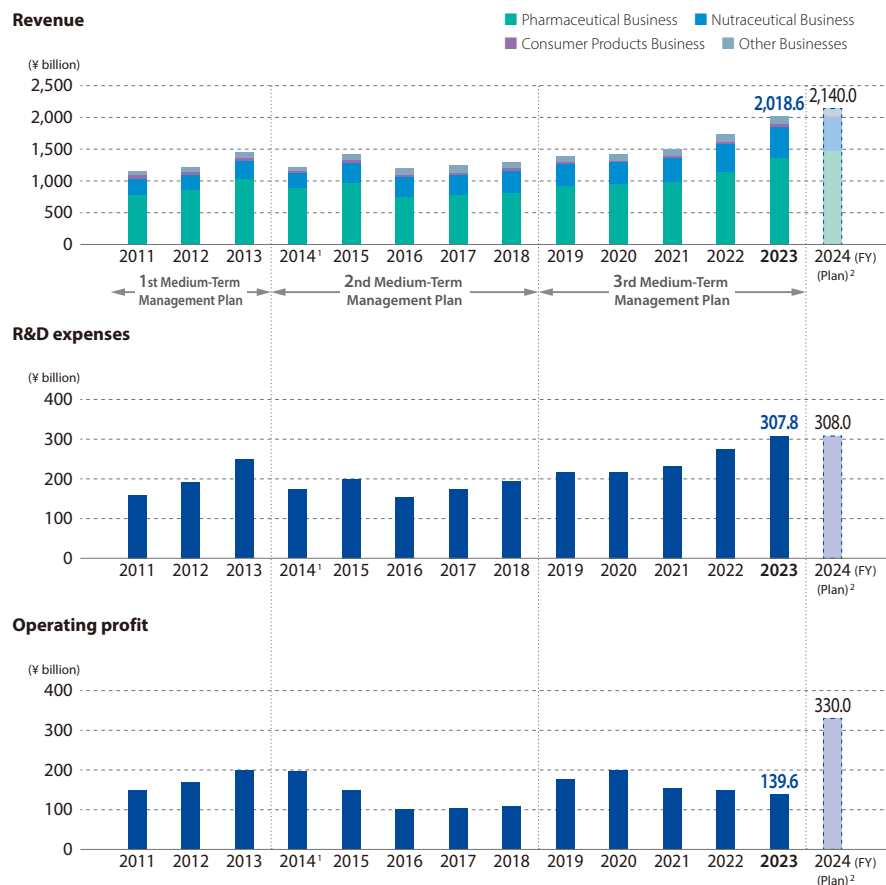
1. Announced February 2024

2. Business profit = Revenue - Cost of sales - Selling, general and administrative expenses + Share of profit of associates - Research and development expenses

## Review of Current and Past Medium-Term Management Plans, and Looking Forward to the Next Medium-Term Management Plan

### Results

The Otsuka group is characterized by the diversity of its businesses. Particularly during the 3rd Medium-Term Management Plan (MTMP) period, we have achieved stable growth as a group through the expansion of our Pharmaceutical Business, including our four Global Products, and the continuous generation of profits from our Nutraceutical Business through the promotion of a high-margin strategy. By supporting this unique Otsuka business model with a stable financial foundation, we aim to make further progress by creating new value.

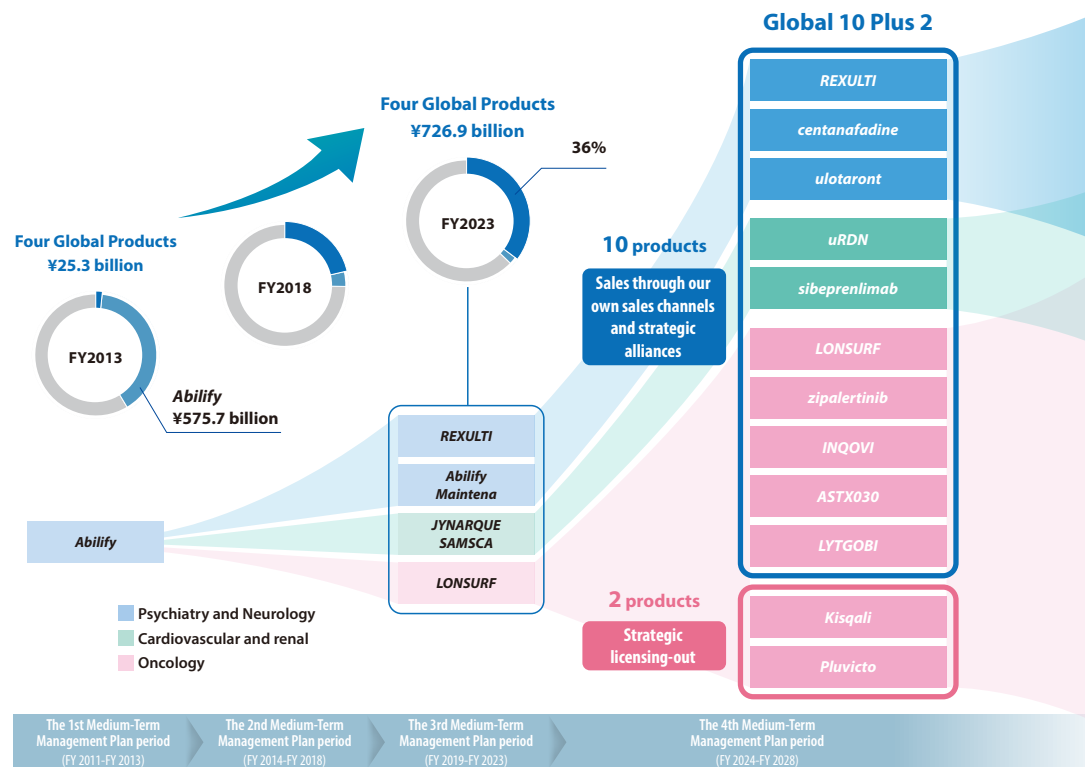


1. For 2014, figures used are for the nine-month period from April 1, 2014 to December 31, 2014 due to a change in the fiscal year end.  
2. Announced February 2024

### Pharmaceutical Business: Global 10 Plus 2 products, next-generation growth drivers for sustainable growth

In 2013, there was a single growth driver, the product *ABILIFY*. After implementing the 2nd MTMP, the goal of which was to diversify our revenue structure, we expanded the number of growth drivers to four products—*REXULTI*, *ABILIFY MAINTENA*, *LONSURF*, and *Samsca/JINARC/JYNARQUE*—through the 3rd MTMP and focused on maximizing value of four Global Products.

In the 3rd MTMP, we also touted the idea of “advancing in the global market as a unique total healthcare company,” and nurtured Global 10 Plus 2 products (see the table below for reference) as next-generation growth drivers with an eye toward the 4th MTMP. During the period of the 4th MTMP, we will maximize the value of Global 10 Plus 2 products and link them to further growth in the 5th MTMP and beyond.



# Outline of 4th Medium-Term Management Plan

## The 4th Medium-Term Management Plan period (FY 2024-FY 2028)

Promotion of new business expansion and investment to generate growth for the next generation  
— Five years of creation and growth —

(Social issues that Otsuka is particularly focused on)



Global environment

Heat | Common global problems



Women's health

Great health needs in various age groups



Aging society with declining birthrates

Aging population is rapidly advancing, especially in developed regions

## Solving social issues and creating a wellbeing future

The 4th Medium-Term Management Plan (MTMP) is positioned as a period of “promotion of new business expansion and investment to generate growth for the next generation—five years of creation and growth.” During that period, we will focus on addressing the social issues of global environment, women's health, and aging society with declining birthrates based on the concept of total healthcare that extends from health prevention and promotion and diagnosis through treatment.

For the Pharmaceutical Business, we forecast revenue of 1,680.0 billion yen in the final year of the plan due to growth for such products as Global 10 Plus 2 products and the minimization of the period of adjustment caused by LOEs.<sup>1</sup> For the Nutraceutical Business, we will propose health solutions for each life stage, centered on the three categories tied to social issues. For this business, we forecast revenue of 620.0 billion yen in the final year of the plan by further maximizing value in each category. Furthermore, we aim to increase corporate value in the long term with an eye toward sustainable growth by striving to implement a “financial strategy to support sustainable growth” and management conscious of cost of capital.

1. Loss of exclusivity

## Outline of the 4th Medium-Term Management Plan

### Performance Targets Establish an advanced stage for revenue/profit growth

- Establish new revenue growth drivers of new product groups
- Minimize the period of adjustment caused by LOEs and transition to a growth stage with a double-digit business profit growth rate

### Business Strategy Establish an advanced stage of business growth stage

- Realize a series of launches of new drugs from the robust late-stage development pipeline
- Continue R&D investments on the scale of ¥300 billion on the back of the highest level of stable financial conditions
- Expand and deepen business areas through new products and services in the pharmaceutical and NC businesses
- Significantly increase the size and quality of profits in the new stage after achieving the MTMP

### Financial Strategy Implement management conscious of cost of capital

- Performance management through ROIC and ROE
- Continue proactive growth investments
- Enhance shareholder returns

## Performance targets | KPI

Unit   ¥ billion	FY2023	FY2026	FY2028
Revenue	2,018.6	2,200.0	2,500.0
Business profit before R&D expenses	620.4	580.0	720.0
Ratio/Revenue	30.7%	26.4%	28.8%
R&D expenses	307.8	310.0	330.0
Business profit <sup>2</sup>	312.6	270.0	390.0
Ratio/Revenue	15.5%	12.3%	15.6%
Operating CF before R&D investments	576.2	540.0	650.0
EPS	¥224.1	¥380	¥550
ROIC	4.8%	≥7.5%	≥9.5%
ROE	5.3%	≥8%	≥10%

Exchange rate assumptions ¥130/\$, ¥140/euro

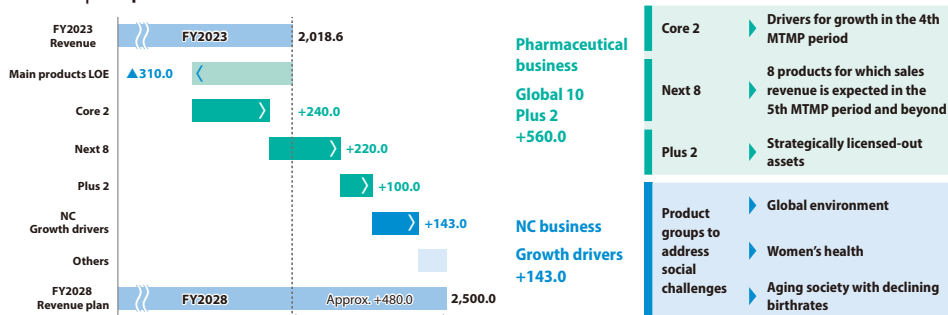
2. Business profit = Revenue – COGS – SGA + share of profit of associates – R&D expenses

## Outline of 4th Medium-Term Management Plan

### Revenue forecast for growth drivers

We plan to offset most of the negative impact due to LOE for major products (310.0 billion yen) through growth of Core 2 products (*REXULTI*, *LONSURF*) that will drive growth during the period of the 4th Medium-Term Management Plan (MTMP). In addition, we plan to generate net growth for Next 8 products (*ulotaront*, *centanafadine*, *uRDN*, *sibeprenlimab*, *LYTGOBI*, *zipalertinib*, *INQOVI*, *ASTX030*), Plus 2 products (*Kisqali*, *Pluvicto*), and NC social problem solving products, which will drive growth in the 4th and 5th MTMPs. As a result, we forecast record revenue of 2,500.0 billion yen in 2028, an increase of almost 480.0 billion yen compared to 2023.

#### Revenue | Comparison between 2023 and 2028



Unit | ¥ billion  
Main products | *ABLIFY MAINTENA*, *JYNARQUE*, *Samsca*

Pharmaceutical business  
Global 10  
Plus 2  
+560.0

NC business  
Growth drivers  
+143.0

- Core 2**
  - Drivers for growth in the 4th MTMP period
- Next 8**
  - 8 products for which sales revenue is expected in the 5th MTMP period and beyond
- Plus 2**
  - Strategically licensed-out assets
- Product groups to address social challenges**
  - Global environment
  - Women's health
  - Aging society with declining birthrates

Core 2 (*REXULTI*, *LONSURF*), Next 8 (*ulotaront*, *centanafadine*, *uRDN*, *sibeprenlimab*, *LYTGOBI*, *zipalertinib*, *INQOVI*, *ASTX030*), Plus 2 (*Kisqali*\*, *Pluvicto*\*)  
\* Royalty: licensed to Novartis

### Growth investments that support sustainable growth

As for R&D expenses, for the Pharmaceutical Business, we expect to invest in not only basic research, which forms core technologies, but also in the psychiatry and neurology area, cardiovascular and renal areas, and oncology area in order to move forward with late-stage clinical development. For the Nutraceutical Business, we will continue to invest in the development of new products. Capital investments are expected to primarily involve investments to reinforce pharmaceutical raw material production capacity and overseas *POCARI SWEAT* production capacity in order to expand the business, and to maintain and update existing facilities with the environment in mind. The basic policy on external asset acquisition, which remains unchanged and is aligned with the long-term strategy, is to make investments in areas that will generate synergies with existing business assets. In particular, it is important to acquire not only drug discovery technologies that make it possible to continually create pipeline products but also a pipeline with global rights in disease areas, primarily in the psychiatry and neurology areas and cardiovascular and renal areas, to implement our growth strategy starting with the 5th MTMP.

### Pharmaceutical business | Strategy outline

Achieve sustainable growth by taking on challenges in new areas

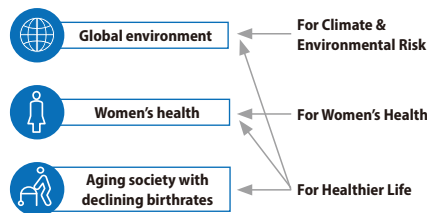
- Build business foundations in innovative new areas
- Create new value leading to "Well-being"
- Develop innovation ecosystem

### NC business | Strategy outline

To become a global company with flexibility  
—Offering health solutions tailored to life stages—

- Contribute to social issue resolutions from a global perspective
- Create and foster the next generation growth drivers
- Continue a high profit structure

#### Nutraceutical Business's solutions from the perspective of social issues



R&D expenses	Purpose of business expansion capital investment	Acquisition of external assets Investment in areas where synergies with management assets can be created, consistent with long-term strategies
Basic research Psychiatry & neurology areas <i>centanafadine</i> , <i>ulotaront</i> , etc. Cardiovascular and renal areas <i>sibeprenlimab</i> etc. Oncology area Products that contribute to growth after the 5th MTMP Development of new NC products	Pharmaceutical Business Research on formulation technology Production facilities for products to be launched Nutraceutical Business Enhance production capacity of overseas <i>POCARI SWEAT</i> Enhance production capacity of <i>Nature Made</i> Maintenance of existing facilities ESG investment	<div style="border: 1px solid blue; border-radius: 15px; padding: 10px; text-align: center;"> <p><b>Novel drug discovery technologies</b></p> <p>Disease areas</p> <p>Psychiatry and neurology areas Cardiovascular and renal areas Oncology area</p> <p>Reinforcement of pipeline in each therapeutic area</p> <p>Aiming to address more social issues</p> </div> <p style="text-align: center; color: blue;"><b>Area</b></p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid blue; padding: 5px;">Assets with global rights</div> <div style="border: 1px solid blue; padding: 5px;">Assets with region's rights such as Japan, Asia, and Europe</div> </div>

# Message from the CFO

**To contribute to solving social problems through Otsuka's innovation to be achieved by our growth as a Total Healthcare Company, we will maximize our cash generation from the organic growth of existing business, which would be also used for investment for future growth, improving capital efficiency and strengthening financial stability.**



*Y. Makino*

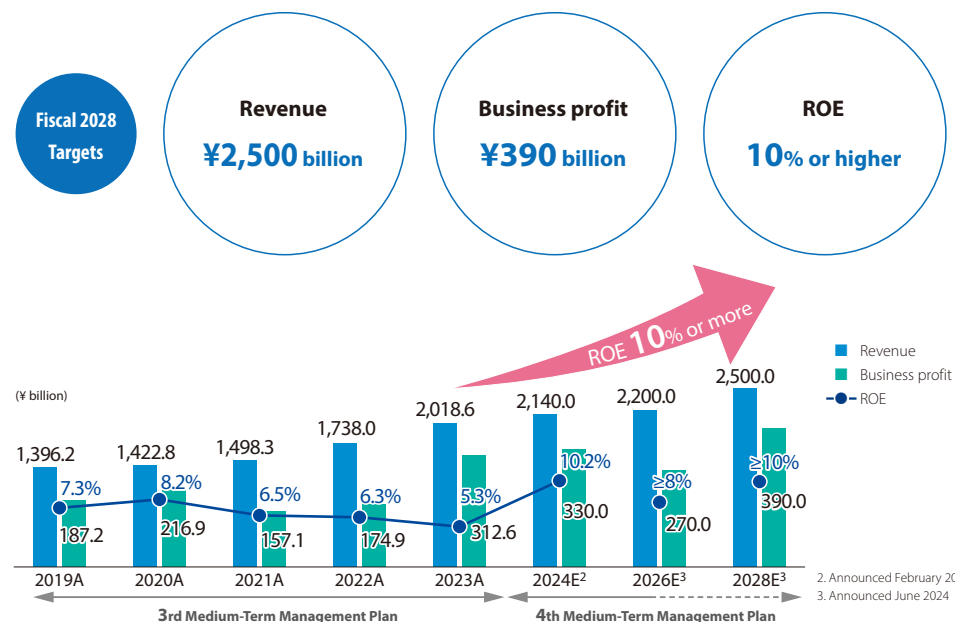
Executive Director, CFO  
Otsuka Holdings Co., Ltd.

## The 3rd Medium-Term Management Plan<sup>1</sup>

1. 3rd Medium-Term Management Plan: 3rd MTMP

The Otsuka group had positioned the period of the 3rd Medium-Term Management Plan (MTMP) as a five-year growth phase for advancing in the global market as a unique total healthcare company. Accordingly, we focused on maintaining sustainable growth by working "Existing Business Value Maximization and New Value Creation," and "Business management with a corporatwide awareness of capital costs" while balancing investment for growth and returns to shareholders. During the period of the 3rd MTMP, although our business was impacted by the external environment, including pandemics, heightened geopolitical risks, and soaring energy and raw material costs, our business grew strongly by leveraging our dual drivers of the Pharmaceutical Business and Nutraceutical Business.

Revenue for FY2023 was over 2 trillion yen, a record high that far exceeded the final year target of 1.7 trillion yen, and the revenue growth rate has been 9.3% on average per year since FY2018. In addition, as a result of our global expansion in the Pharmaceutical Business and Nutraceutical Business, the ratio of overseas revenue increased from 50% to 67%, showing steady expansion. Business profit totaled over 300 billion yen, far exceeding the final year target of 200 billion yen, and the growth rate has been 20.9% on average per year since FY2018, well above the target of more than 10%.



## Message from the CFO

In the Pharmaceutical Business, we were able to maximize business value through the contribution of four Global Products (*ABILIFY MAINTENA*, *REXULTI*, *Samsca/JINARC/JYNARQUE* and *LONSURF*), which are growth drivers, and new products launched in the past five years. In the Nutraceutical Business, the growth driver *Nature Made* grew significantly to become a 100 billion yen brand. We believe this is due to the growing trend of health consciousness of consumers and our activities to date have earned the brand high reliability. Meanwhile, we are leveraging the *POCARI SWEAT* brand strength we have built to increase sales and earnings in the Asia-Pacific region. Due to this growth of *Nature Made* and *POCARI SWEAT* and other factors, the ratio of overseas sales in the Nutraceutical Business increased by 9.3 percentage points to 66.0% in 2023 from 56.7% in 2018. Revenue from the growth drivers of both businesses accounted for 87% of the 726.6 billion yen increase in consolidated revenue, contributing significantly to the positive performance of the 3rd MTMP period.

The 3rd MTMP period has been positioned as a period for introducing the practice of “Business management with a corporatewide awareness of capital costs.” Accordingly, we have introduced ROIC management as a financial framework to continue sustainable growth over the medium to long term and to have our stakeholders understand and value our challenge to contribute to society. We have been promoting the introduction of ROIC management and its penetration among group companies. We have made steady efforts to improve asset efficiency, by having our group companies understand the ROIC concept and promoting KPI management to improve ROIC, maximizing business value by optimizing SG&A expenses, and reviewing our cross-shareholdings structure and its reduction and utilizing idle real estate, which have steadily yielded results. The average ROIC over the past five years was 5.9%, exceeding the cost of capital (WACC) of 5.5% originally projected in the 3rd MTMP period. By generating cash through maximizing the value of existing businesses, we were able to increase cash and cash equivalents by approximately 200 billion yen during the period of the 3rd MTMP and to secure shareholder returns and investment for future growth in the 4th MTMP period, while implementing the investment for growth to create new value.

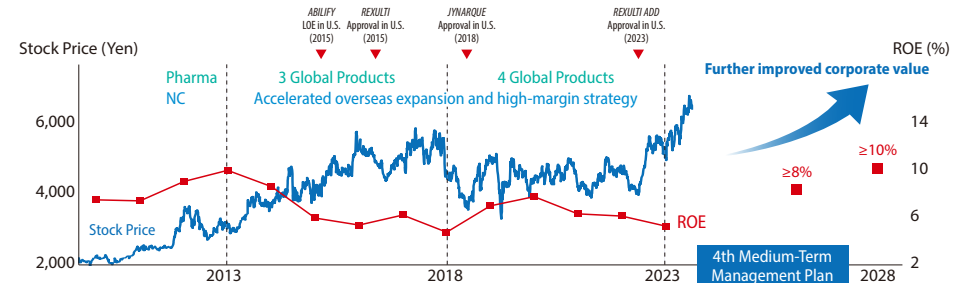
### Financial Policy in the 4th Medium-Term Management Plan<sup>1</sup>

1. 4th Medium-Term Management Plan: 4th MTMP

#### Financial Targets

The Otsuka group has been investing the operating cash flow before R&D investments generated by its business activities in its pipeline, basic drug discovery technology, brand value of NC products and human resource development, which are all sources of growth, thereby generating new cash to fund future growth. Repeating this cycle of investment and growth has enabled us to achieve growth and enhance our corporate value. Looking at our stock price performance since listing on the Tokyo Stock Exchange, we have seen a steady increase in corporate value, which would imply our management

#### Stock Price Performance Over Time



decision to expand business area and to quickly recover from the impact of LOE in the Pharmaceutical Business has been accepted in the stock market.

When we went public in December 2010, many concerns were raised in the market about the US patent expiration of *ABILIFY* in 2015. To respond to such concerns, since the expiration of the *ABILIFY* patent, we have diversified our revenue structure by developing 3 Global Products (*ABILIFY MAINTENA*, *REXULTI*, and *Samsca/JINARC*), next-generation products such as *LONSURF*, as well as implementing the high-margin strategy on NC business. Furthermore, the 3rd MTMP period has been positioned as a preparation period to deal with the patent expirations of *ABILIFY MAINTENA* and *JYNARQUE* and this challenge through nurturing the next growth drivers. Through these measures, as well as expanding business and improving earnings through investment for growth, we were able to steadily enhance our ability to generate stable cash exceeding WACC.

In the 4th MTMP period, we will actively make investment for future growth to mitigate the impact from loss of exclusivity on Pharmaceutical Business and we will further develop our diversified business from a capital efficiency perspective. For FY2028 targets, we aim to achieve revenue of 2,500 billion yen, business profit before R&D expenses of 720 billion yen, business profit of 390 billion yen, EPS of 550 yen, operating cash flow before R&D investments of 650 billion yen, and capital efficiency with ROE of 10% or more, and ROIC of 9.5% or more.

#### Cash Allocation

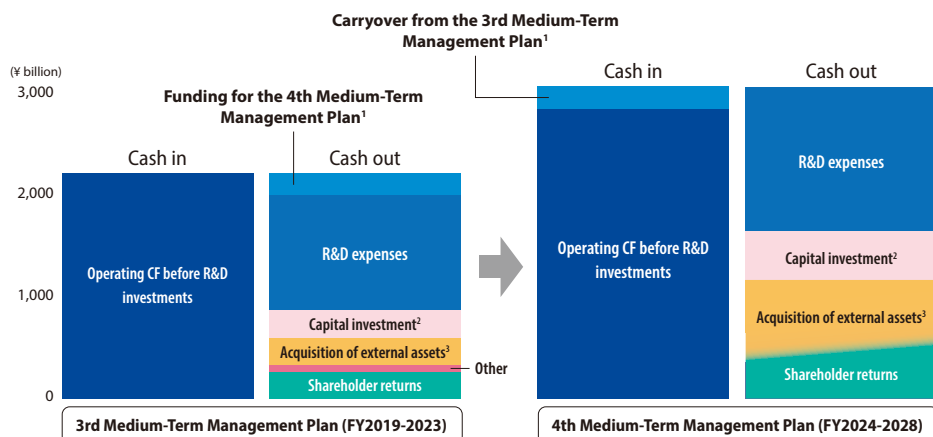
As a result of favorable business profits and efforts to improve asset efficiency during the period of the 3rd MTMP, operating cash flow before R&D investments for the five-year period totaled 2,336.5 billion yen. The generated cash was used for proactive R&D investments totaling 1,181.6 billion yen and growth investment totaling 496.9 billion yen, including capital expenditures for acquiring new pipelines and overseas expansion, while 278.5 billion yen was paid out to shareholders as dividends. Furthermore, cash and cash equivalents increased by 228.3 billion yen to 513.3 billion yen due to stable cash generation not only from Pharmaceutical Business but also from the other business segments particularly Nutraceutical Business.

## Message from the CFO

In the 4th MTMP we plan to secure funds of approximately 3,200 billion yen, which exceeds the amount in the 3rd MTMP period, by adding approximately 200 billion yen in cash and cash equivalents, an increase from the 3rd MTMP period, to the approximately 3 trillion yen in operating cash flow before R&D investments to be generated over the five-year period. About 1.5 trillion yen for R&D is planned to be invested mainly in the fields of psychiatry and neurology, oncology, and cardiovascular and renal disease to advance basic research and late-stage clinical development that will become fundamental technologies for drug discovery in the Pharmaceutical Business. In addition, in the Nutraceutical Business we plan to continuously invest in the development of new products. Of the approximately 500 billion yen in capital expenditures, about half will be used for investment for growth, such as the construction of a plant to increase overseas *POCARI SWEAT* production capacity, while the remaining half will be invested in the maintenance and renewal of existing facilities in an environmentally friendly manner.

In acquisition of external assets, we will acquire pipelines that will contribute to growth in the 5th and 6th MTMPs, as well as acquire and collaborate on drug discovery technologies to continuously generate pipelines, and expand pipelines in disease areas that can contribute to social issues more broadly, based on our current strengths. From a regional perspective, we will not only expand our global pipeline including the U.S., but also acquire external assets in specific regions such as Japan, Asia, and Europe, taking into consideration the acquisition of pipelines that will allow us to utilize our own sales network.

### Cash Allocation in the 3rd and 4th Medium-Term Management Plans



1. Investment for growth and funds to shareholder returns for 4th MTMP  
 2. ESG investments, maintenance of existing facilities and business expansion aimed at capital investment  
 3. Acquisition of external assets for investment for growth

## Initiatives to Enhance Corporate Value

### Framework of Financial Strategies to Support New Value Creation

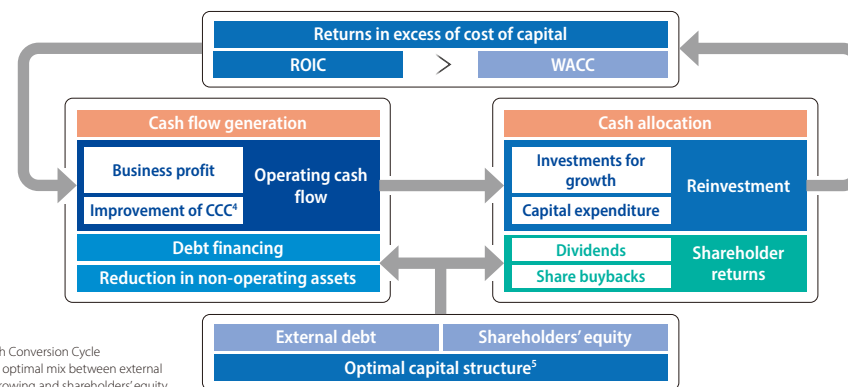
#### Source of Funds for Investment for Growth

In principle, investment for growth are funded through the reinvestment of cash returns generated from businesses, and funds within the Otsuka group are effectively used across business segments, using funds from the cash management system in Japan, North America, and China. Where external procurement of cash is required, we are always prepared to implement the full range of options, including commercial paper, corporate bonds, bank loans, and share issues. To ensure our ability to act in a timely manner on business opportunities when they arise, we are prepared for the risk that financial uncertainty in the market may cause some procurement methods to become unavailable. We are also considering the issuance of green bonds during the period of the 4th MTMP as not only a part of our efforts to promote sustainability management but also new procurement options in addition to the current available ones.

#### Allocation of Funds for Investment for Growth

At the Otsuka group, we see investment as a vehicle for pursuing innovation that enables us to contribute to society, and will continue to take on investment projects that enhance corporate value and contribute to society. The basic policy for acquiring external assets remains the same: invest in areas that are consistent with long-term strategies and that can generate synergies with existing management assets. As specific examples of reallocation of investments, in the Pharmaceutical Business, we will not only acquire and collaborate on drug discovery technologies that will continuously generate pipelines, and

### Framework of Financial Strategies



4. Cash Conversion Cycle  
 5. The optimal mix between external borrowing and shareholders' equity

## Message from the CFO

make sustained R&D investments to strengthen products and pipelines in the priority areas of psychiatry and neurology, oncology, and cardiovascular and renal diseases, but also invest in *uRDN* therapy, a new approach in the medical device business. In the Nutraceutical Business segment, in addition to investments to expand sales channels to new areas, we are investing in brand building by promoting the value of new products and strengthening our supply chain.

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

We believe that ROIC management, which supports Otsuka's innovation, is an important measure not only to improve capital efficiency in the short term, but also to contribute to medium- to long-term corporate value. From a financial perspective, we believe that establishing a stable financial framework will make us continue working on "what only Otsuka can do," which would support driving innovation and eventually result in contribution to society. During the period of the 4th MTMP, we will plan our cost of capital at 6% and fully implement ROIC management. To improve ROIC, maximizing cash return from operations: operating cash flow before R&D investments, and optimizing invested capital will be key measures.

### Maximizing Cash Return

As for maximizing cash return, we will set KPI targets according to business characteristics such as therapeutics, clinical nutrition, and medical devices in pharmaceutical business, and for NC business, we will set KPI targets according to business development in growth market areas, and will improve KPI management for promoting business.

At the same time, we will also practice cost control, which we have been continuously implementing since the previous MTMP period, and enhancing shared service initiatives in each area.

### Optimizing Invested Capital

Optimization of invested capital will be practiced in three main areas: asset efficiency, financial stability and efficiency, and shareholder returns.

#### (1) Asset efficiency

For asset efficiency, we aim to improve ROA by strengthening control of business assets with a view to optimizing group companies as a whole, including the use of business assets based on stronger investment discipline. We also aim to improve CCC<sup>1</sup> by strengthening control of working capital through optimization of accounts receivable and inventory management. As for non-business assets, we will periodically test and reclassify the cross-shareholdings structure to improve the quality of invested capital.

#### (2) Financial stability and efficiency

We will maintain our R&I rating of AA- or higher and establish financial stability by diversifying financing

sources, including the issuance of green bonds when external financing is required, and by practicing financial risk management such as foreign exchange forward contracts.

Financial efficiency will be improved by reducing interest-bearing debt as a result of controlling standby funds needed for operations through the use of CMS.

#### (3) Shareholder returns

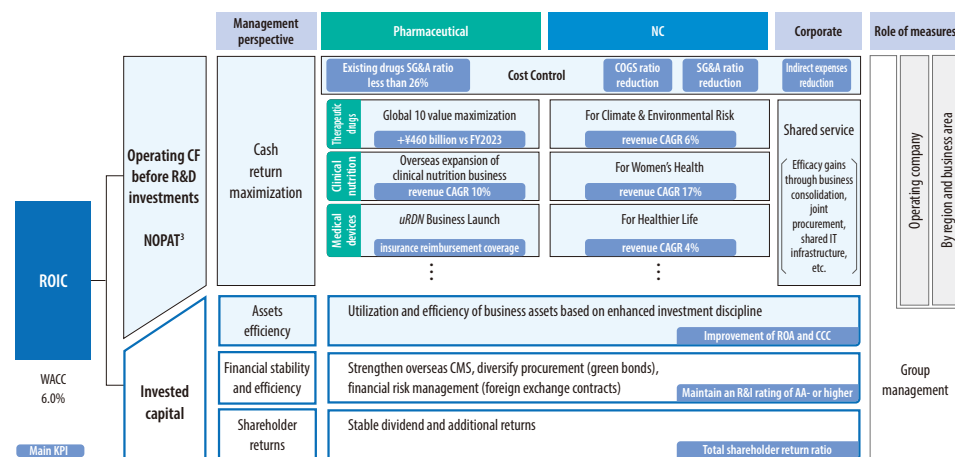
While our basic policy for shareholder returns is to make dividend payouts stably and continuously, we carefully consider the amount of dividends, comprehensively weigh issues such as appropriate levels of retained cash for investment for growth, maintain a solid financial standing, and achieve the optimal capital structure.

Thanks to the results from our investment for growth made up to the period of the 3rd MTMP, we have decided to increase the year-end dividend for FY2023, as we are now in a position to expect sustainable growth during the 4th MTMP period. In addition to stable and continuous dividend payments, we are planning approximately 50 billion yen of share buybacks during the period of the 4th MTMP (as of July 2024). We plan to flexibly consider additional approaches for shareholder returns during the 4th MTMP period from various perspectives, including the outlook for sustainable growth after the 5th MTMP period, the upward cash generation from organic growth of business during the 4th MTMP period, and the status of the total return ratio.<sup>2</sup>

1. Cash Conversion Cycle  
2. (Cash dividend + Stock buy-back)/Net profit \* 100

### Otsuka Group ROIC Management

Aim to achieve a ROIC of over 9.5% by FY2028 by balancing growth investment and the creation of economic value exceeding WACC

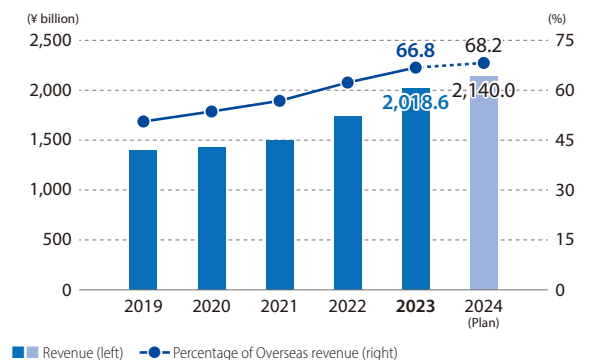


3. Net Operating Profit After Tax



# Financial and Non-Financial Highlights

## Revenue and Percentage of Overseas Revenue

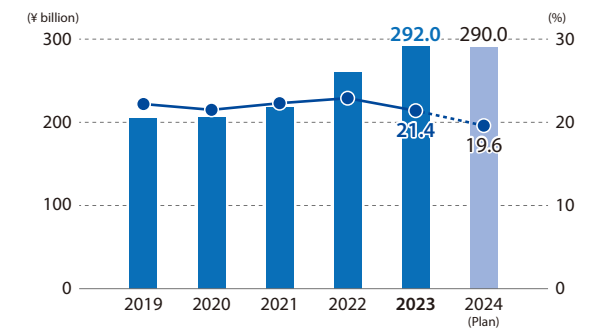


■ Revenue (left) ● Percentage of Overseas revenue (right)

Revenue continues to grow, especially in the four Global Products of the Pharmaceutical Business and the three Major Brands and three Nurture Brands of the Nutraceutical Business.

The percentage of overseas revenue has been increasing yearly, especially with the growth in North America.

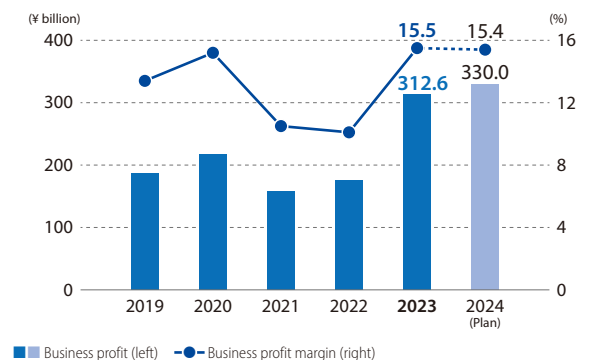
## Pharmaceutical Business R&D Expenses, R&D Ratio (Percentage of Revenue)



■ R&D expenses (left) ● R&D ratio (right)

In anticipation of growth from the 4th Medium-Term Management Plan (MTMP), we are continuing to invest in R&D at a high level, focusing on next-generation growth drivers to strengthen our products and pipeline in our priority areas of psychiatry and neurology, oncology, and cardiovascular and renal disease.

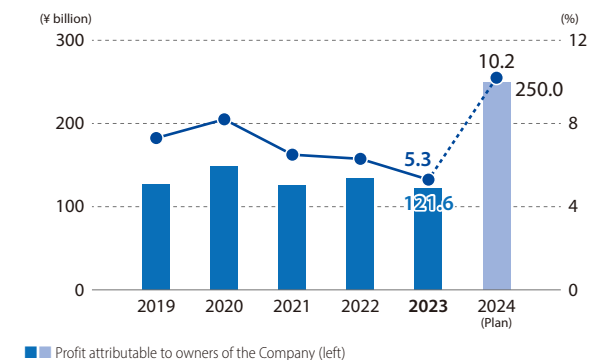
## Business Profit, Business Profit Margin (Percentage of Revenue)



■ Business profit (left) ● Business profit margin (right)

Business profit was affected by higher raw material and energy costs, as well as by the COVID-19 pandemic, but increased due to sales growth, as well as stronger sales efforts and control of SG&A expenses.

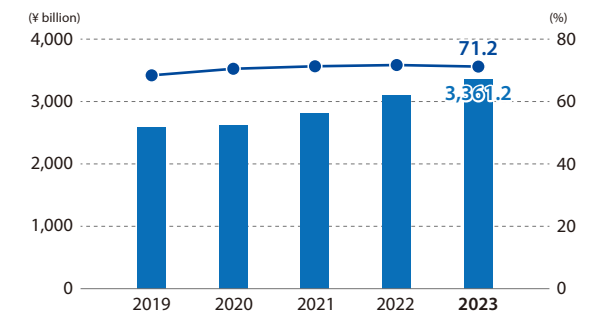
## Profit Attributable to Owners of the Company, Return on Equity Attributable to Owners of the Company (ROE)



■ Profit attributable to owners of the Company (left) ● Return on equity attributable to owners of the Company (ROE) (right)

In 2023, ROE was 5.3% due to the impact of impairment loss on AVP-786. ROE for the 2024 plan is expected to be 10.2%, an increase of 4.9% over the previous year. By conducting business management with a corporate-wide awareness of capital cost, we aim to improve capital efficiency and achieve more than the plan.

## Total Assets, Ratio of Equity Attributable to Owners of the Company to Total Assets

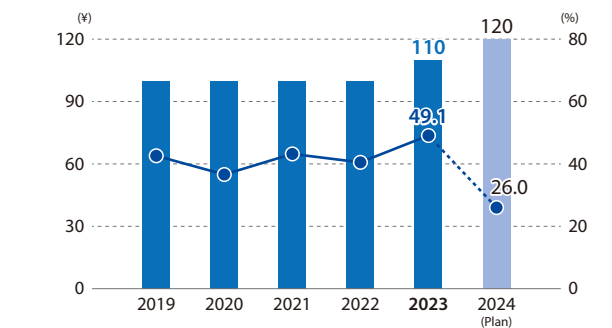


■ Total assets (left) ● Ratio of equity attributable to owners of the Company to total assets (right)

Assets have increased due to aggressive overseas business development as well as the impact of the yen's depreciation.

The ratio of equity attributable to owners of the parent company has remained stable financially.

## Annual Dividend per Share, Dividend Payout Ratio



■ Annual dividend per share (left) ● Dividend payout ratio (right)

Our basic policy for shareholder returns is to pay stable dividends in line with profit growth. Starting from the end of fiscal 2024, we plan on increasing the annual dividend to 120 yen and will examine additional shareholder returns during the period of the 4th MTMP based on the outlook for sustainable growth starting with the 5th MTMP.

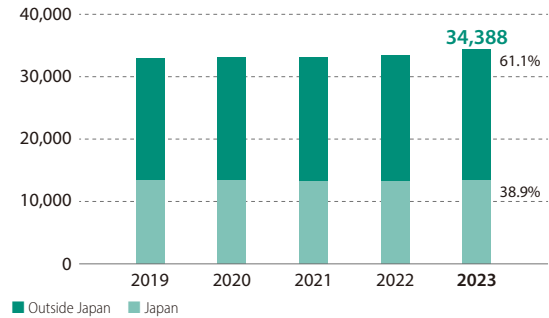
## Financial and Non-Financial Highlights

See here for sustainability data.

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



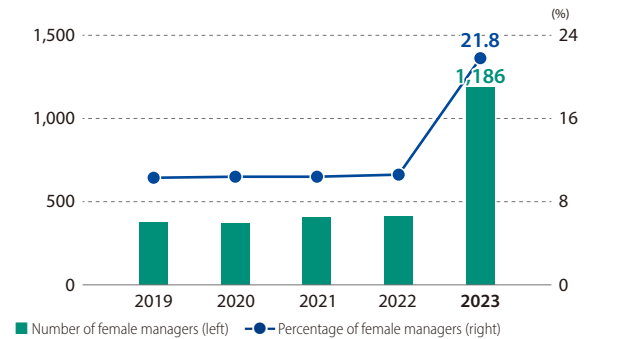
### Number of Employees



Data scope: Otsuka Holdings and its 168 consolidated subsidiaries

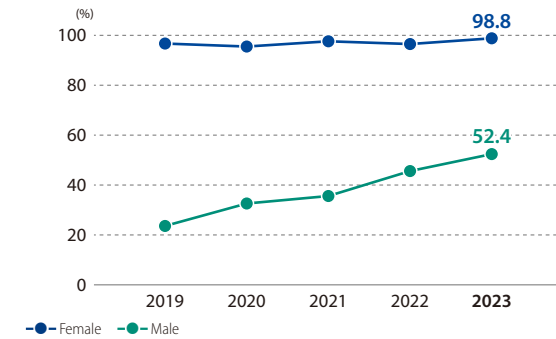
Sixty percent of our employees are active overseas and we are promoting global expansion.

### Number of Female Managers, Percentage of Female Managers<sup>1</sup>



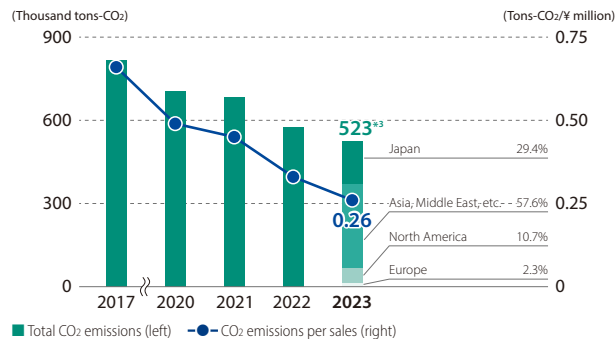
The number and rate of female managers increased as a result of revising the scope of "managers" at overseas operating companies in fiscal 2023.

### Number of Employees Taking Parental Leave<sup>2</sup>



Seminars to encourage employees to change their attitudes, and the implementation of a new system to encourage male employees to take parental leave, have led to an increase in the uptake rate.

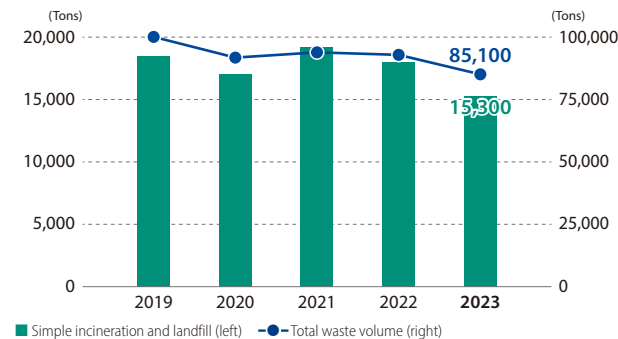
### CO<sub>2</sub> Emissions, CO<sub>2</sub> Emissions per Sales



Scope: All production sites of the consolidated Otsuka group

CO<sub>2</sub> emissions declined 9.2% from the previous fiscal year for several reasons, including the broader introduction of CO<sub>2</sub>-free electricity and solar power generation equipment and the switch in fuels.

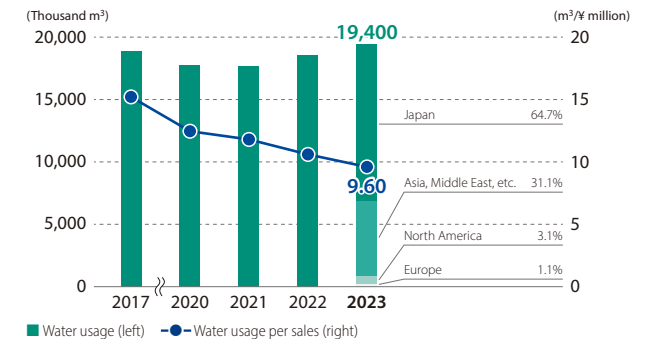
### Simple Incineration and Landfill Volume, Total Waste Volume



Scope: All production sites of the consolidated Otsuka group

Total global emissions were down 8.4% from the previous year, while simple incineration and landfill emission volume were down 17.3% from 2019.

### Water Usage, Water Usage per Sales



Scope: All production sites of the consolidated Otsuka group

Global water usage increased 4.9% from the previous fiscal year for several reasons, including greater production volume at domestic factories, but water usage per sales fell 9.7% from the previous fiscal year.

1. 2. Scope of the data: (Fiscal 2017–2018) Six companies: Otsuka Pharmaceutical, Otsuka Pharmaceutical Factory, Taiho Pharmaceutical, Otsuka Warehouse, Otsuka Chemical, and Otsuka Foods

(Fiscal 2019) Nine companies: the six companies above plus Otsuka Pharmaceutical Development & Commercialization, Otsuka America Pharmaceutical, and Pharmavite

(Fiscal 2020) Eleven companies: the nine companies above plus Otsuka Holdings and Otsuka Medical Devices

(Fiscal 2021) Nineteen companies: the eleven companies above plus Otsuka Electronics, Otsuka Techno, Okayama Taiho Pharmaceutical, Otsuka Packaging Industries, Otsuka Ohmi Ceramics, Higashiyama Film, Otsuka Wellness Vending, and JIMRO

(Fiscal 2022) Twenty companies: the nineteen companies above and Otsuka Pharmaceutical Europe

(Fiscal 2023) Twenty-three companies: the twenty companies above and J. O. Pharma, EN Otsuka Pharmaceutical, and Otsuka Business Support

2. Only for the above companies that are domestic companies.

3. Includes improvement in CO<sub>2</sub> emissions due to the use of the IEA's coefficients.

# Business Strategy | At a Glance

The Otsuka group operates its business in four segments: the Pharmaceutical Business, the Nutraceutical Business, the Consumer Products Business, and Other Businesses.

## Pharmaceutical Business



- Therapeutic drugs
- Diagnostics
- Clinical nutrition
- Medical devices
- Fine chemicals

## Nutraceutical Business



- Functional beverages and foods
- OTC products and quasi-drugs
- Cosmetics

## Consumer Products Business



- Beverages
- Foods
- Wine

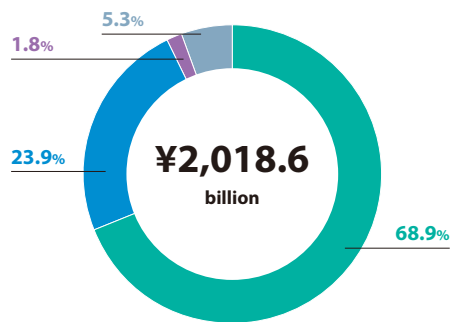
## Other Businesses



- Chemicals
- Warehouse and distribution
- Packaging
- Electronic equipment

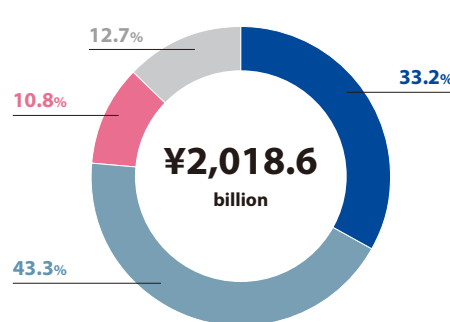
### Revenue\*

By Business Segment (Fiscal 2023)



- Pharmaceutical Business
- Nutraceutical Business
- Consumer Products Business
- Other Businesses

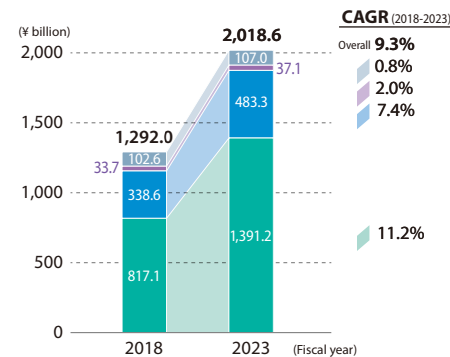
By Region (Fiscal 2023)



- Japan
- North America
- Europe
- Other

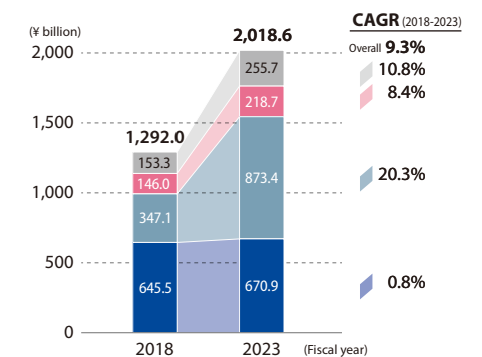
### Revenue and CAGR\*

By Business Segment



- Pharmaceutical Business
- Nutraceutical Business
- Consumer Products Business
- Other Businesses

By Region



- Japan
- North America
- Europe
- Other

\* Revenue from sales to external customers

\* Fiscal 2023 performance was revised to reflect changes in how revenue from inter-segment transactions and other items are recorded starting in fiscal 2024.

## Business Strategy



Contribute to the Health and Well-being of People Around the World

### Related SDGs



<https://www.otsuka.com/en/rd/business/pharmaceuticals/>



## Pharmaceutical Business

### Outline of the 4th Medium-Term Management Plan strategy

Achieve sustainable growth by taking on challenges in new areas

- Build business foundations in innovative new areas
- Create new value leading to “Well-being”
- Develop innovation ecosystem

### Fiscal 2028 Performance Targets

Revenue plan: 1,680 billion yen  
Business profit plan: 320.0 billion yen

### Fiscal 2023 Results

Revenue: 1,391.2 billion yen  
Business profit: 282.1 billion yen

## Summary of 3rd Medium-Term Management Plan and Outline of 4th Medium-Term Management Plan

Under the 3rd Medium-Term Management Plan (MTMP), we moved forward with various initiatives based on the strategic framework of maximizing value of existing businesses, challenging new frontiers as “only Otsuka Can Do”, and generating innovation from creative and diverse research platforms. We were able to increase revenue from our four Global Products, *ABILIFY MAINTENA*, *REXULTI*, *Samsca/JINARC/JYNARQUE*, and *LONSURF*, which are positioned as growth drivers in this business. As a result, we achieved the targets in the 3rd MTMP two years ahead of schedule. As a result, the revenue from our pharmaceutical business in fiscal year 2023, the final year of the plan, reached 1,391.2 billion yen and business profit amounted to 282.1 billion yen.

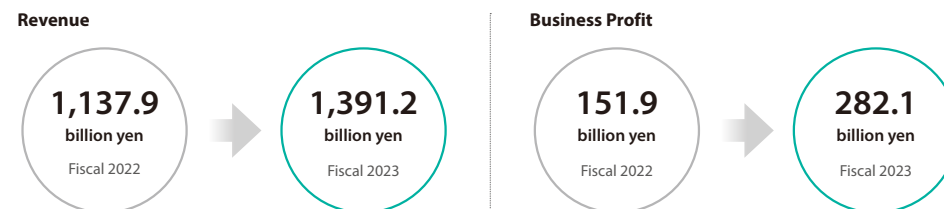
### Growth Driven by Four Global Products

The expansion of overseas areas and additional indications for Four Global Products, as well as efforts to raise awareness of the convenience of the formulations positively contributed, resulting in revenue of 726.9 billion yen in fiscal 2023, up 17.4% from the previous year. We achieved the target of 480.0 billion yen for the final year of the 3rd MTMP in fiscal 2021, and business continued to grow significantly in fiscal 2023.

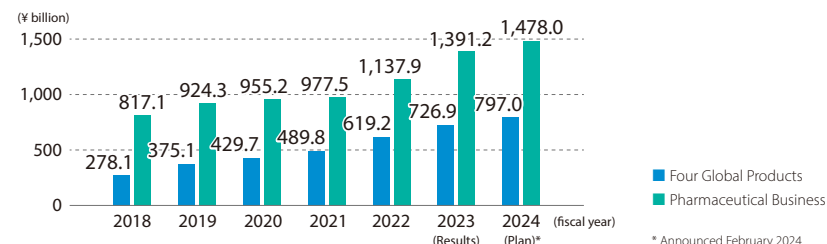
### Outline of the Fourth Medium-term Management Plan and Social issues continuing to be tackled

For the Otsuka group, R&D expenses totaled 1,181.6 billion yen over the five years of the 3rd MTMP as we continued to strengthen products and our pipeline, resulting in progress in the development of 69 products, 16 of which gained approval. The R&D efforts during the 3rd MTMP have contributed to nurturing the “Global 10 Plus 2” products, which are the next-generation growth drivers that will support Otsuka’s future growth. Through the 4th MTMP we will move forward with further maximizing the value of Global 10 Plus 2 products. To contribute to the solution of social issues, we will continue to

aggressively undertake R&D, confront global social issues with the unique product lineup that only Otsuka can offer, and provide well-being to people throughout the world as a total healthcare company.



### Pharmaceutical Business: Progress in Revenue



### Four Global Products revenue

(¥ billion)	FY2022 revenue	FY2023 revenue	Year-on-year	FY2024 revenue plan*	Growth rate
<i>ABILIFY MAINTENA</i>	165.4	202.5	+22.4%	206.0	+1.7%
<i>REXULTI</i>	169.1	212.5	+25.6%	256.0	+20.5%
<i>Samsca/JINARC/JYNARQUE</i>	227.2	231.8	+2.0%	240.0	+3.6%
<i>LONSURF</i>	57.5	80.1	+39.3%	95.0	+18.6%
<b>Total</b>	<b>619.2</b>	<b>726.9</b>	<b>+17.4%</b>	<b>797.0</b>	<b>+9.7%</b>

\* Announced February 2024

## Business Strategy ■ Pharmaceutical Business

### Pharmaceutical Business Outline and Areas

The Otsuka group is focusing on the priority fields of psychiatry and neurology, oncology, and cardiovascular and renal areas based on the topic of "unmet medical needs." In addition, we provide comprehensive healthcare services that extend from diagnosis to treatment through initiatives in a wide range of areas and businesses, including the digestive system, ophthalmology, diagnostics, the IV solutions business, and the medical device business.

### Business Strategy for FY2024

#### Nurturing Global 10 Plus 2 Products that Can Support Otsuka's Future Growth

Through the 3rd MTMP, we generated numerous results as we worked to achieve sustainable growth starting with the 4th MTMP. Through continued aggressive R&D and progress with our pipeline based on

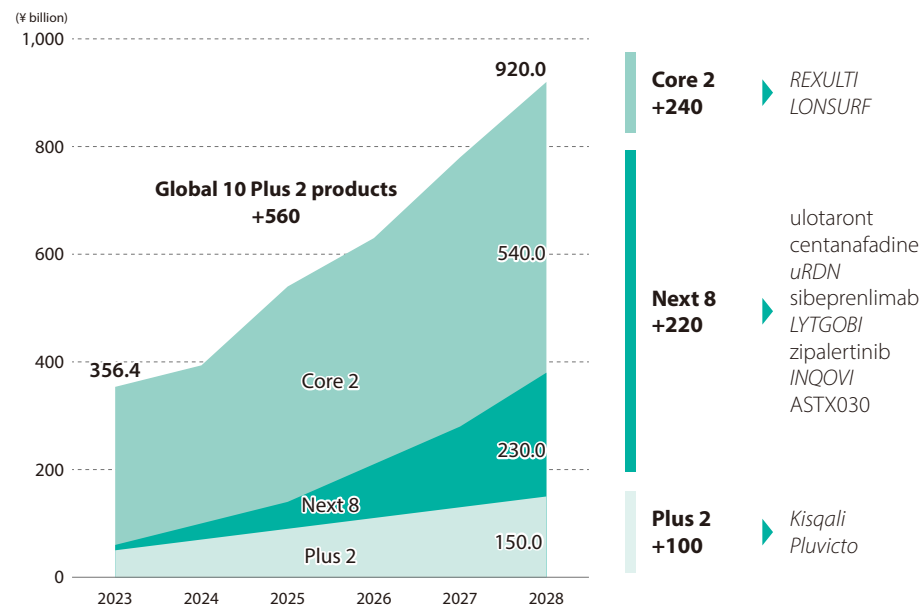
in-house development and strategic collaborations, we nourished the Global 10 Plus 2 products, the next-generation growth drivers that can support Otsuka's future growth, which consist of ten in-house developed products and two strategically licensed-out products. Of these, five in-house developed products and two strategically licensed-out products have already been launched. As for the remaining five in-house developed products, we have already obtained positive results from Phase 3 studies for one and forecast strong sales growth for the product.

In the 4th MTMP, we plan to launch multiple new products in addition to the Global 10 Plus 2 products and will strive to minimize the expected impact of the expiration of the exclusivity period ("patent cliff") for major products and ensure the realization of sustainable growth starting with the 4th MTMP. In particular, we forecast total revenue for the entire Pharmaceutical Business at 1,680.0 billion yen in fiscal 2028 (average annual growth of 3.8%) as a result of growth in revenue from such products as Global 10 Plus 2 products (revenue of 920.0 billion yen in fiscal 2028) despite an adjustment phase in the short term due to loss of exclusivity (LOE).

#### Results of Strategic Investments During 3rd Medium-Term Management Plan

Results	Concrete examples
Implemented aggressive R&D investments (cumulative investment of <b>1,181.6 billion yen</b> )	
<b>Promoted development of new drugs</b> Promoted development of <b>69 products</b> → Obtained approval for <b>16 products</b>	Main products that won approval or indications in 2023 • REXULTI • ABILIFY ASIMTUFII • LONSURF • Ultrasound Renal Denervation System (uRDN)
<b>Developed innovative new drugs</b> Granted Breakthrough Therapy and Breakthrough Device Designation from U.S. FDA <b>4 products</b>	• zipalertinib • futibatinib • Ultrasound Renal Denervation System (uRDN) • sibeprenlimab (February 2024)
<b>Strengthened pipeline through M&amp;As and strategic collaboration (13 products)</b>	• ulotaront • AB122/AB154
<b>Strategically licensed-out assets</b>	• Kisqali, Pluvicto
<b>Expand drug discovery platform (mergers and alliances)</b>	• Opened Otsuka Pharmaceutical Osaka Research Center for Drug Discovery • Collaborated with academia

#### Revenue plan for Global 10 Plus 2 products



## Business Strategy ■ Pharmaceutical Business

### Otsuka Group's Priority Areas

#### Psychiatry and Neurology Area

In the area of psychiatry and neurology, we have a portfolio of development items and products with high potential for schizophrenia, bipolar disorder, and major depressive disorder. For example, in addition to brexpiprazole (product name: *REXULTI*), which was approved in the U.S. for agitation associated with dementia due to Alzheimer's disease, we are moving forward with the development of centanafadine for attention-deficit hyperactivity disorder (ADHD) and major depressive disorder. Moreover, there are concerns about the increase in Alzheimer's disease as the world population ages. The agitation due to this disease affects not just the patient's quality of life; it also places a strain on family members and caregivers, and is one reason patients have to enter nursing home, not live with their families.

The causes and mechanisms are not fully understood, which makes the discovery of new drugs extremely difficult. Hence, many psychiatric and neurological disorders are still left without an established satisfactory treatment. 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 in this area. As a leading company in this area, we are meeting unmet needs through comprehensive initiatives that are not limited to drugs but also include such products as recovery support programs for affected people using treatment apps and VR that employ digital technology.

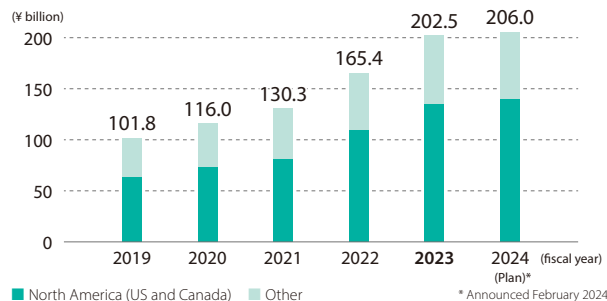
#### ■ ABILIFY MAINTENA / ABILIFY ASIMTUFII

##### aripiprazole | Antipsychotic long-acting injectable

In fiscal 2023, U.S. sales increased as a result of not only growth in prescriptions, mainly due to face-to-face detailing activities that promote the efficacy of the product for bipolar I disorder and schizophrenia



Revenue of ABILIFY MAINTENA / ABILIFY ASIMTUFII



patients, who have problems with medication adherence, but also the impact of exchange rate fluctuations. In addition, Japan sales are steadily growing because we strengthened information provision for bipolar I disorder in addition to schizophrenia.

In April 2023, aripiprazole 2-month long-acting injectable received marketing approval under the product name *ABILIFY ASIMTUFII* from the U.S. FDA for the treatment of schizophrenia and bipolar I disorder.

#### ■ REXULTI

##### brexpiprazole | Atypical antipsychotics

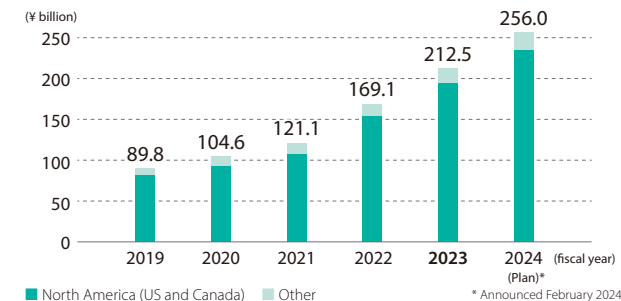
In the U.S., in addition to adjunctive therapy for major depressive disorder and a treatment for schizophrenia, approval was obtained to use brexpiprazole as a therapy for agitation associated with dementia due to Alzheimer's disease in May 2023. In addition to moving forward with activities to raise awareness of agitation associated with dementia due to Alzheimer's disease, we are undertaking DTC<sup>1</sup> advertising. In fiscal 2023, sales rose because of an increase in the number of prescriptions due to stronger face-to-face detailing activities and impact of exchange rate fluctuations. In Japan, sales rose as the number of new prescriptions increased due to stronger detailing activities related to its use for schizophrenia.

Currently, multiple clinical trials are underway to further contribute to unmet therapeutic areas in psychiatric and neurological disorders. In Japan, additional approval as an effective treatment option for depression and depressive states was obtained in December 2023.

1. Direct to Consumer: advertising of pharmaceuticals that make direct appeals to patients



Revenue of REXULTI





Contribute to the Health and Well-being of People Around the World

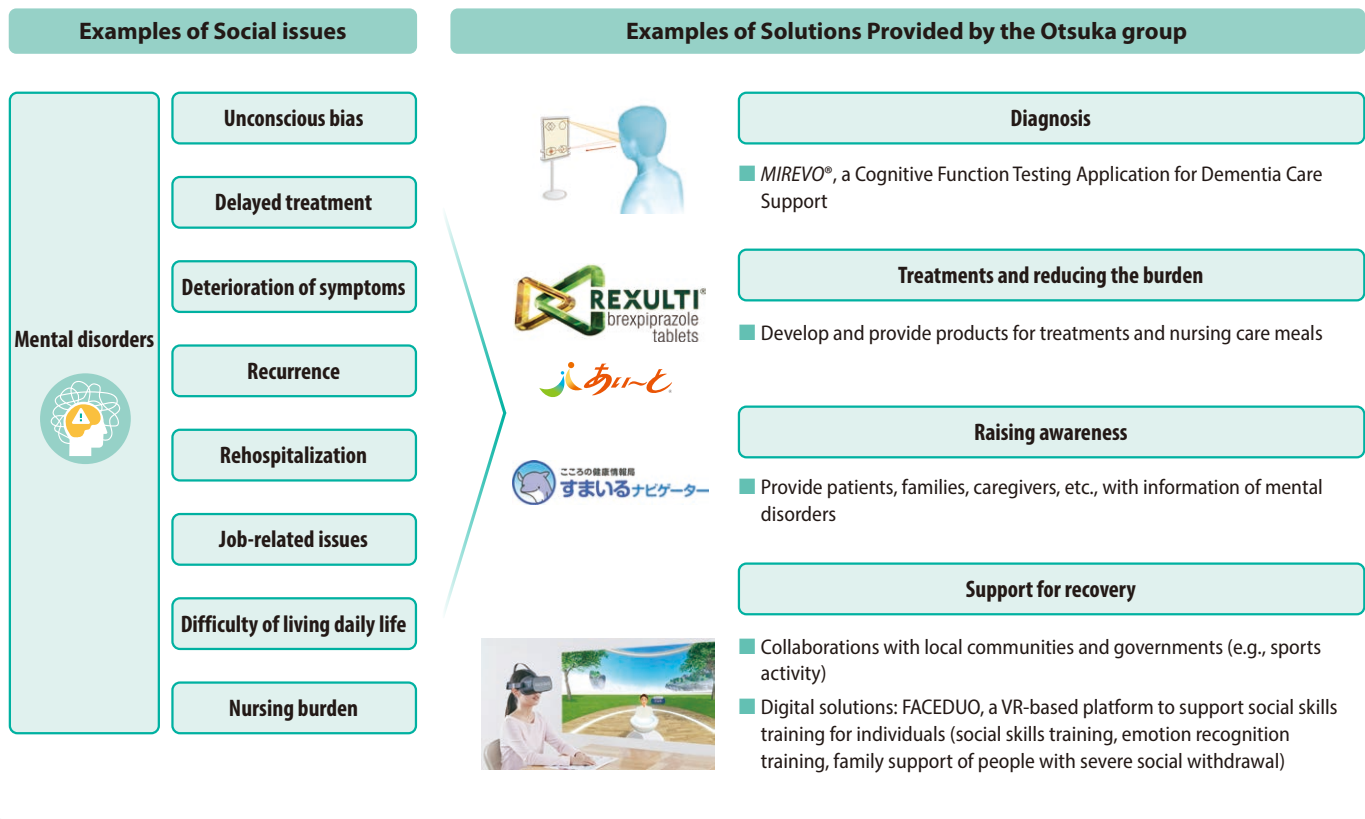
<https://www.otsuka.com/en/rd/business/pharmaceuticals/>



## Providing Comprehensive Solutions to Improve Mental Health

### Basic Policy

The World Health Organization (WHO) defines mental health as “a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community,” and elements such as treatment of mental disorders and rehabilitation are included. In addition, patient centricity such as making decisions of treatment policies through collaboration with patients and medical professionals are considered important solutions against social issues. The Otsuka group continues to implement initiatives to improve the mental health of patients with mental disorders.



### Developing innovative products to realize a future society that values well-being

#### Otsuka Pharmaceutical's initiatives targeting agitation\* associated with dementia due to Alzheimer's disease



**Mary Hobart**  
Otsuka Pharmaceutical Development & Commercialization Inc.  
Senior Vice President,  
Global R&D Evidence  
(Regulatory Affairs OPDC)

I joined Otsuka Pharmaceuticals in 1999 and have been involved in the development of REXULTI since 2008.

In 2023, the approval of REXULTI as the first drug in the U.S. for agitation associated with dementia due to

Alzheimer's disease was a great honor. Although clinical trials targeting these patients were challenging and time-consuming, we confirmed the effectiveness and safety of the drug.

Agitation, which about half of patients with Alzheimer's disease suffer from, is considered a major social issue because it not only places a heavy burden on caregivers and lowers the quality of life of patients, their families, and caregivers, but is also one reason why patients cannot live with their families and have to be placed in nursing facilities.

The approval of REXULTI as a treatment for agitation associated with dementia due to Alzheimer's disease represents an important milestone for patients and caregivers confronting this complicated challenge. Providing new treatment options in response to the unmet needs of people living with this condition underlines the commitment of the Otsuka group in a profound way.

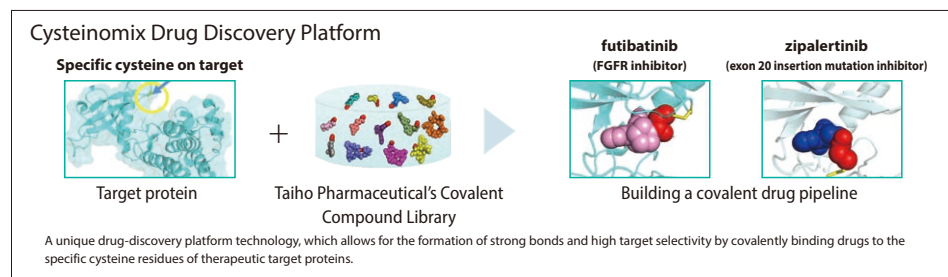
\* Agitation: A state that impedes either a patient's daily life, social life, or human relations and is indicated by either increased activity, such as wandering or repetitive actions, whether aggressive or non-aggressive, or aggressive speech or behavior.

## Business Strategy ■ Pharmaceutical Business

### Oncology Area

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

Our proprietary drug discovery platform technologies, including biochemical modulation drug discovery, which Taiho Pharmaceuticals quickly started to work on, Cysteinomix Drug Discovery, which is distinguished by specific covalent modification of therapeutic targets, and Astex Pharmaceuticals' fragment drug discovery,<sup>1</sup> support the creation of a broad product portfolio. For example, futibatinib (product name: *LYTGOBI*) was discovered using the Cysteinomix Drug Discovery Platform. In September 2022, the U.S. FDA granted approval for its use with "previously treated unresectable locally advanced or metastatic intrahepatic cholangiocarcinoma accompanying FGFR2 gene fusions or other rearrangement," and was approved for biliary tract cancer in Japan and for bile duct cancer in Europe in 2023. Similarly, zipalertinib was discovered using the Cysteinomix Drug Discovery Platform and is currently undergoing Phase 3 studies for non-small cell lung cancer with EGFR exon 20 insertion mutation. In addition, ASTX727 (product name: *INQOVI/INAQOVI*) and ASTX030, which were discovered by Astex Pharmaceuticals, are undergoing clinical trials as an oral drug for hematological cancer.



The Otsuka group is also accelerating its drug development to resolve unmet needs through collaboration with partner companies. Furthermore, we look for opportunities for collaboration with promising startups through corporate venture capital, thereby expanding our development pipelines in cancer immunotherapy and other areas, and acquiring innovative drug discovery platform technologies. Meanwhile, primarily through 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 strength to bolster global operations and enhance business value.

1. 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.

### ■ LONSURF

#### trifluridine/tipiracil | Anticancer agent

As of December 31, 2023, the drug had been approved in 100 countries and regions for the treatment of unresectable advanced or recurrent colorectal cancer, and prescriptions are increasing. In the U.S., sales grew dramatically because of its approval for additional indications as a bevacizumab combination therapy for colorectal cancer in August 2023, its recommendation as a combination therapy based on NCCN Guidelines,<sup>2</sup> and exchange rate fluctuations. In Europe, too, it was approved for additional indications for bevacizumab combination therapy for colorectal cancer in July 2023. In Japan, sales are also rising steadily due to greater recognition as a bevacizumab combination therapy on account of its reference in influential research articles.

2. Cancer treatment guidelines used broadly throughout the world

### Creating innovative drugs to realize a future society that values well-being

#### To contribute in People's "Today and Every Day" ~Taking on the challenges in new cancer drug development~

Taiho Pharmaceutical has adopted the communication slogan "Today and Every Day." Its goal is to make contributions through drugs so that, for example, cancer patients can receive appropriate treatment while enjoying their usual daily lives with their families.

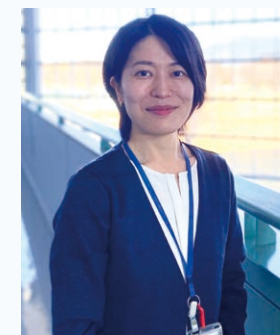
As for new drug development, its focus is on cysteinomix drug discovery. This technology, which bonds specified amino acids into new drugs, has demonstrated both strong bonding strength and high selectivity. Focusing on this value in the early stages, we have been building the cysteinomix compound library for more than a decade. As a result, we are now working on multiple development projects based on cysteinomix drug discovery.

We confront numerous issues in our drug discovery activities. It is a continual process of trial and error because there are no clear right answers and success conditions. Our drug discovery projects are established through collaboration among numerous areas. We will resolve each issue by forming teams of specialists and sharing opinions from various perspectives. Working as unified team, we passionately strive to deliver new therapeutic options to patients.

We achieve this goal by showing the high efficacy and safety of the new drugs that we create through our activities for difficult-to-treat cancers that still lack satisfactory treatments and other immunity-related diseases.

For more information on "Today and Every Day," click here.

<https://www.taiho.co.jp/en/company/slogan/>



**Chihoko Yoshimura**

Taiho Pharmaceutical Co., Ltd. R&D Division  
Daiichi Lab Director



## Business Strategy ■ Pharmaceutical Business

### Cardiovascular and Renal Areas

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

In the cardiovascular and renal areas, we are not only reinforcing in-house drug discovery but also aggressively making growth investments, including acquiring Visterra Inc., which possesses a pipeline in the renal area. We are working to address diseases caused by renal failure that dramatically lowers the QOL of patients with such drugs as *JINARC/JYNARQUE*, a treatment for autosomal dominant polycystic kidney disease (ADPKD), and sibeprenlimab, a treatment for IgA nephropathy that is under development.

A concrete result of these initiatives was that we conducted a clinical trial of sibeprenlimab, which was created by Visterra Inc., for IgA nephropathy and obtained breakthrough therapy designation<sup>1</sup> by the U.S. FDA in February 2024. In addition, we are moving forward with the development of medical devices that place less of a burden on the body through a creative approach that combines pharmaceuticals and medical device know-how. In November 2023, we obtained approval from the U.S. FDA for the use of Ultrasound Renal Denervation System as a new treatment option for patients with hypertension who are unable to sufficiently manage their hypertension with the lifestyle improvements and antihypertensive drug treatment.

1. A system to accelerate the development and screening of drugs used to treat serious or life-threatening diseases. It is available for drugs for which there is significant preliminary clinical evidence for key clinical items compared to existing treatment methods.

### ■ Ultrasound Renal Denervation System

#### *uRDN* | New hypertension therapy option

The Ultrasound Renal Denervation system (*uRDN*) was first approved by the U.S. FDA in November 2023 as an adjunctive treatment option for hypertension when lifestyle modification and medications have not adequately controlled a patient blood pressure. It is a novel ultrasound-based renal denervation technology designed to lower blood pressure by denervating the sympathetic nerves surrounding the renal arteries, reducing the overactivity that can lead to hypertension.

While a number of antihypertensive drugs have been developed and used for many years, a considerable number of patients who are treated for hypertension remain uncontrolled, which over time, can lead to serious heart issues. In three global, independently powered, sham-controlled<sup>2</sup> randomized clinical trials of the *uRDN* conducted in the U.S. and Europe, the efficacy and safety of the *uRDN* have been demonstrated. This novel treatment option can revolutionize the existing way hypertension has been treated.

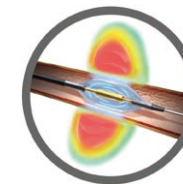
In the U.S., the system has been used in a number of facilities since the day after the FDA approval and has spread throughout the U.S. In Europe, it has been introduced in major countries after receiving the CE Mark.<sup>3</sup> In Japan, a clinical trial is currently underway.

2. Placebo procedures

3. The CE marking represents a manufacturer's declaration that products comply with the EU legislation and meet high safety, health, and environmental protection requirements.

#### *uRDN* features

- Designed to lower blood pressure by using ultrasound to denervate the sympathetic nerves surrounding the renal arteries in a circumferential and deep level, reducing the overactivity that can lead to hypertension
- Circulating sterile water through a balloon catheter during procedure to help protect the renal artery wall
- Simple operation and short procedure time



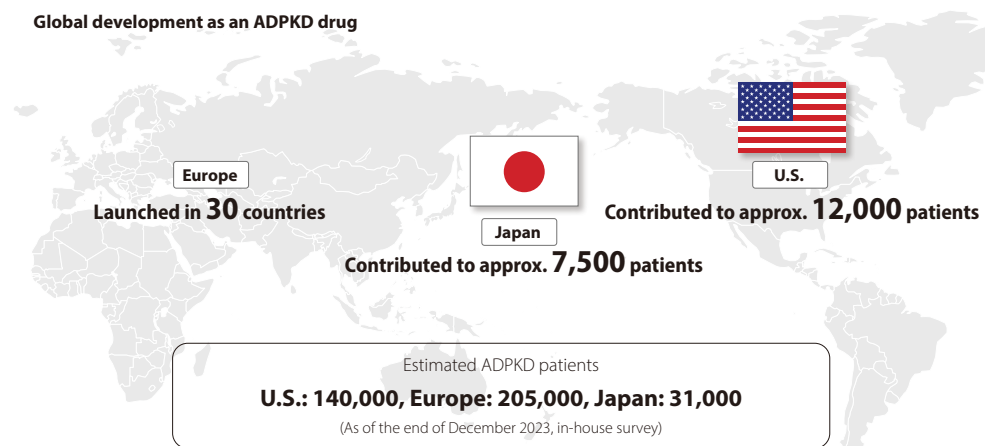
### ■ *Samsca/JINARC/JYNARQUE*

#### tolvaptan | V<sub>2</sub>-receptor antagonist

In 2003, the number of prescriptions of *Samsca/JINARC/JYNARQUE* for autosomal dominant polycystic kidney disease (ADPKD) increased with more than 10,000 patients having been treated with the drug. On the other hand, sales decreased due to the impact of the switch to generics for the treatment for fluid retention in patients with heart failure and hepatic cirrhosis. Even in the U.S., where the drug is sold as a treatment for hyponatremia, there was a dramatic decline in revenue in response to the introduction of generics.

For *JINARC/JYNARQUE*, there was a dramatic increase in sales because of an increase in the number of prescriptions due to continuous efforts to raise awareness of its use as a ADPKD drug and the provision of information on clinical data, as well as the impact of exchange rate fluctuations.

#### Global development as an ADPKD drug





Contribute to the Health and Well-being of People Around the World

## Challenge of Unmet Medical Needs (Tuberculosis)

### Basic Policy

Good health is a universal desire. In the Otsuka group, we work every day to help healthcare professionals around the world prevent and treat illness, and to help ordinary people maintain and improve their health. Numerous challenges remain, including protracted infectious disease outbreaks, underdeveloped medical infrastructure, and insufficient effective treatment options. We approach these issues by identifying what it is that only Otsuka can do, with a particular focus on working to address unmet medical needs. Among them, tuberculosis (TB), one of the world's three major infectious diseases, is one of the most important areas, and various efforts are underway to eradicate it.

### Challenge to increase access to pharmaceuticals and related initiatives

TB is one of the world's three major infectious diseases, along with HIV/AIDS and malaria. In 2022, there were more than 10 million cases and 1.3 million deaths worldwide from TB, a serious disease that is the second most common cause of death by infectious disease after COVID-19. Multidrug-resistant TB (MDR-TB) cannot be treated with several of the top drug options, making it difficult to treat and a major issue. In some countries, being infected with TB results in discrimination and prejudices against patients and their families, which results not only in infections growing more serious as infected people are reluctant to get diagnosed but also to the disease spreading. This is given as one of the reasons why there has been little decline in the number of TB patients.

Against this backdrop, Otsuka Pharmaceutical created the TB drug delamanid after more than 40 years of research and development. And by working with the Global Drug Facility (GDF) of the Stop TB Partnership, an organization that enables sustainable procurement in developing countries, such as in Africa and Asia, where many patients live, we have brought access to TB drugs and diagnostics to almost all countries that require therapies. We are also moving forward with R&D on new drugs and aiming to contribute to the elimination of TB and improvements in public health throughout the world.

Other initiatives include participation in the Global Health Innovative Technology Fund (GHIT Fund), a public-private partnership established in Japan to fight infectious diseases worldwide; cooperation with programs run by organizations such as Médecins Sans Frontières; securing support from the Bill & Melinda Gates Foundation to develop new TB treatments; and alliances with global companies with strengths in public health in regions where we do not have a



Number of patients provided with delamanid  
(As of December 2023)

More than 100,000 in total  
Can be used in more than 120 countries  
worldwide

presence. We are working to contribute to the health of people worldwide through activities that involve many stakeholders.

### Working to eliminate Antimicrobial Resistance (AMR<sup>1</sup>)

Otsuka Pharmaceutical formulated the Responsible Access Program to prevent the outbreak of delamanid-resistant TB and to promote proper use of the drug.

This system for proper use, our initiatives to provide global access, and continuing R&D on antimicrobial-resistant TB have been highly praised in the *Antimicrobial Resistance Benchmark* report issued by the Access to Medicine Foundation, which analyzes initiatives to improve access to important drugs in low middle income countries.

1. AMR (antimicrobial resistance)

### Indonesia's efforts to eliminate TB

According to the World Health Organization (WHO), Indonesia is one of the worst countries in terms of TB because as of 2022, it had the second largest number of TB patients after India. The Indonesian government recognizes the serious nature of this situation and launched activities to eliminate TB by 2030, which Otsuka Pharmaceutical is supporting. In particular, the TB elimination activities at workplaces, which were launched in July 2022 and involve numerous corporations, were highly praised, and in March 2024, PT Otsuka Indonesia and PT Amerta Indah Otsuka were presented with the Exemplar Award by the Ending Workplace Tuberculosis (EWTB) Initiative, which was established primarily by the World Economic Forum.



Received 2023 Exemplar Award

## Business Strategy



Contribute to the Health and Well-being of People Around the World

### Related SDGs



<https://www.otsuka.com/en/rd/business/nutraceuticals/>



## Nutraceutical Business

### Outline of the 4th Medium-Term Management Plan strategy

- Contribute to social issue resolutions from a global perspective
- Create and foster the next generation growth drivers
- Continue a high profit structure

### Fiscal 2028 Performance Targets

Revenue plan: ¥620.0 billion  
Business profit plan: ¥90.0 billion

### Fiscal 2023 Results

Revenue: ¥483.5 billion  
Business profit: ¥60.5 billion

## Summary of 3rd Medium-Term Management Plan

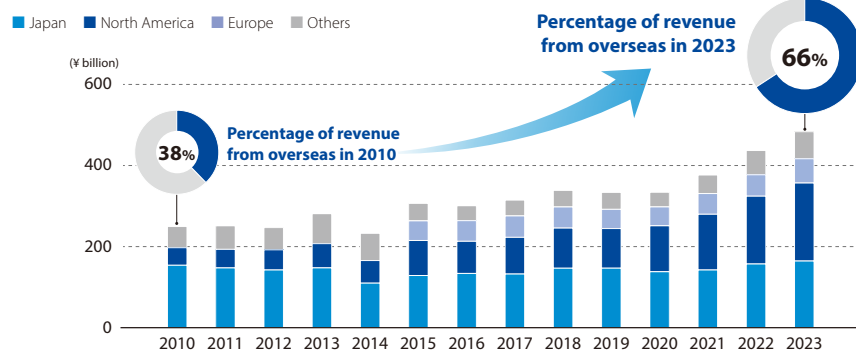
### Search for growth and further acceleration of global expansion

During the 3rd Medium-Term Management Plan (MTMP), it was possible to increase sales, particularly overseas, through strong growth for *POCARI SWEAT*, *Nature Made*, and the Nutrition & Santé brand, our three Major Brands, and *Daiya*, *EQUELLE*, and *BODYMAINTÉ*, our three Nurture Brands.

### Increase value of our product line-up of unique brands

Of the three Major Brands, *POCARI SWEAT* and *Nature Made* made firm contributions overseas, making it possible to exceed 3rd MTMP targets. Sales volume of *POCARI SWEAT* rose, primarily in Asia, on account of its brand image established over many years and greater awareness of the importance of hydration and electrolyte replenishment as a result of educational activities tailored to the particular region's culture and conditions. Sales of *Nature Made* rose dramatically in the U.S. because of the high trust in the brand and its quality.

### Accelerating Global Expansion—Trends in Overseas Revenue



Notes: For the fiscal year ended December 31, 2014, figures for the nine-month period from April 1 to December 31, 2014 are noted due to a change in the fiscal year end. European revenue prior to 2014 is included in Other Businesses.

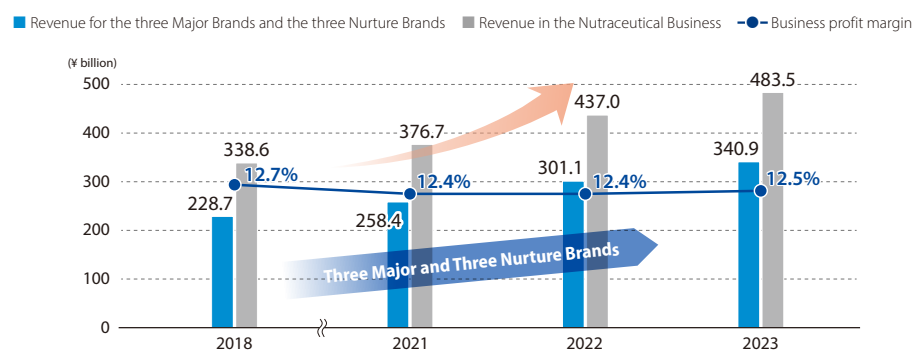
## High margin strategy based on brand value

As a result of the marketing strategy to communicate globally the product value, it was possible to maintain the business profit margin above 12% during the period of the 3rd MTMP, which exceeded the plan's target of 10%. We are also making upfront investments in fields and areas to expand the scale of business while maintaining a business profit margin of at least 12%.

## Outline of 4th Medium-Term Management Plan and social issues that we continue to tackle

Through the 4th MTMP, we will tackle social issues in each area and region and contribute to the health and well-being of people around the world as a total healthcare company through Otsuka's unique product line-up.

### Revenue During the 3rd Medium-Term Management Plan



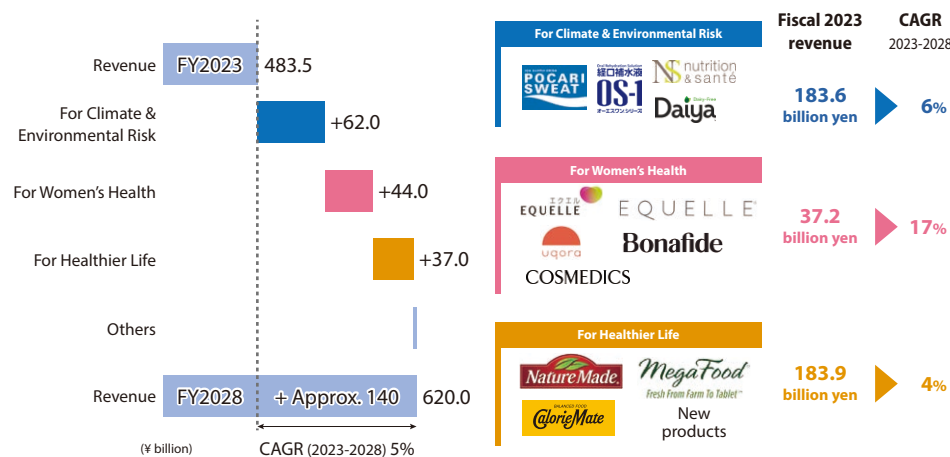
## Business Strategy ■ Nutraceutical Business

### Nutraceutical Business Outline and Area

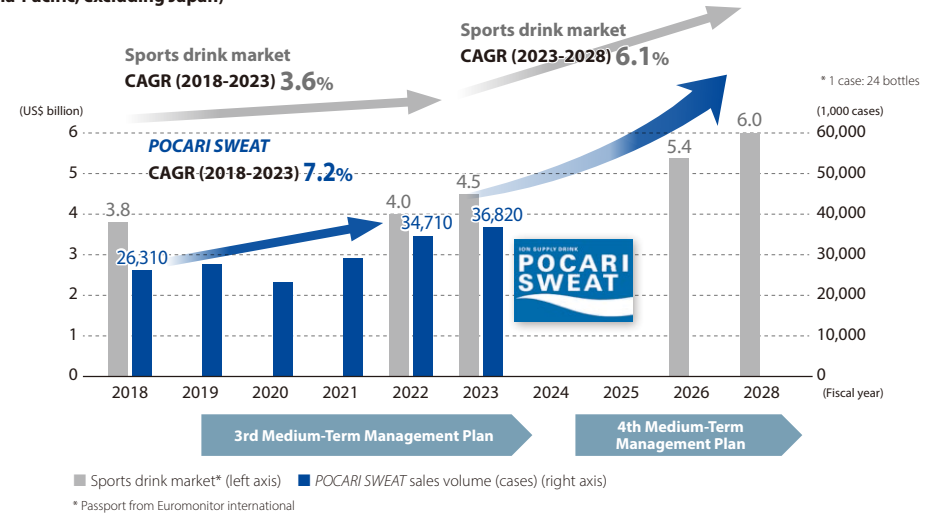
Otsuka group's Nutraceutical Business conducts business centered on such products as functional beverages, functional foods, and supplements, which support the maintenance and improvement of day-to-day health. Leveraging our know-how acquired through the Pharmaceutical Business, we are working to develop unique products based on scientific evidence and conduct business globally, including in Asia, U.S., Europe, Middle East, and Africa.

### 4th Medium-Term Management Plan Revenue Plan for Three Categories that Are Addressing the Social Issues

- For Climate & Environmental Risk | Develop overseas *POCARI SWEAT* business to be a ¥100 billion brand
- For Women's Health | Build growth foundation to become a leader by developing the category, mainly in North America
- For Healthier Life | Further maximize value with unique product line-up geared toward life stages of consumers



Sports drink market and *POCARI SWEAT* sales volume results (Asia-Pacific, excluding Japan)



### ■ *POCARI SWEAT*

Aim to maximize value in global markets, particularly ones in the fast growing Asia-Pacific region

During the period of the 3rd MTMP, overseas *POCARI SWEAT* sales grew at a CAGR of about 16%, resulting in overseas sales accounting for more than 50% of sales in 2023. The Asia-Pacific sports drink market, where the Otsuka group operates its *POCARI SWEAT* business, contracted temporarily in 2020 because of restrictions on consumers' movement due to the COVID-19 pandemic, but since then, it has continued to grow due to strong health awareness. Sales are forecast to grow at a CAGR of 6% between 2023 and 2028. Because of this forecast of continued strong growth, we aim to further spread the brand in existing markets and expand into new markets by educating consumers of the importance of hydration and electrolyte replenishment.

We are taking on the challenge of nurturing *POCARI SWEAT* into a 100.0 billion yen brand overseas through growth, mainly in Asian countries such as China and Indonesia.



Contribute to the Health and Well-being of People Around the World

## Striving for Zero Incidents of Heat Disorders

### Basic Policy

As it is said that “the earth has entered the age of global boiling,” global warming has become serious. Related social issues, such as heat disorders, are causing incidents and threatening our daily lives. The Otsuka group has been striving to achieve zero incidents due to heat disorders over the past 30 years. We are working with various stakeholders to maintain and enhance our well-being, in addition to providing diagnosis and treatments, as a total healthcare company.

### Training Heat Disorders Prevention Ambassador Course

To prevent heat disorders, it is not only necessary for individuals to be aware of the risks, but also to encourage many people to help prevent such disorders through appropriate information. At



Otsuka Pharmaceutical, we hold a Heat Disorders Prevention Ambassador Course (support provided by the Ministry of the Environment, the Ministry of Education, Culture, Sports, Science and Technology, and the Ministry of Agriculture, Forestry and Fisheries), at which it is possible for local governments, schools, corporations, and other organizations to acquire specialized knowledge necessary to conduct heat disorders prevention educational and promotion activities. Participants who complete the seminar are certified as Heat Disorders Prevention Ambassadors and play a role in expanding the range of people who provide warnings to those around them.

### Expansion of Otsuka's heat disorders prevention activities



#### Local governments, ministries, and agencies

- Concluded first collaboration agreement with the Ministry of the Environment to reduce incidents involving heat disorders
- Concluded a collaboration agreement with the Environmental Restoration and Conservation Agency to promote heat disorders prevention
- Concluded a collaboration agreement with local governments throughout Japan, including 47 prefectures, related to heat disorders prevention measures
- Held an expert conference to promote heat disorders prevention in local communities in collaboration with local governments and related organizations



#### Elderly people

- Conducted educational activities on heat disorders prevention in collaboration with numerous entities, including public health centers and community comprehensive support centers throughout Japan
- Conducted educational activities in collaboration with welfare volunteers of local governments



#### Corporations and workplaces

- Collaborated with the Japan Industrial Safety & Health Association to create booklets on the prevention of heat disorders
- Dispatched instructors to seminars and conducted on-site courses on preventing heat disorders in workplaces with hot environments



#### Children and students

- Our employees conducted explanatory meetings on heat disorders and their prevention at various venues including classes, all-school meetings, and club activities
- We collaborated with local governments, school boards, and other entities to provide teaching materials, allowing teachers from elementary to high school to conduct related activities
- We collaborated with local experts, including trainers and sports nutritionists, to hold seminars for educators and guardians



#### Sport activities

- Initiated collaboration with the Japan Sport Association to help prevent heat disorders, coinciding with the formation of the association's Study Group for Prevention of Heat Disorders in Sports Activities
- Collaborated in creating and widely distributing the Guidebook for Prevention of Heat Disorders in Sports Activities, published by the Japan Sports Association
- Cosponsored the creation of hydration-focused sports manuals for rugby, soccer, judo, track and field, and baseball teams

## Business Strategy ■ Nutraceutical Business

### ■ Nature Made

Striving to generate additional growth particularly in the U.S. based on brand strength and high trust in quality

While it continues to conduct R&D on supplements, Pharmavite LLC manufactures and sells *Nature Made* brand products, which were first launched in California, U.S., in 1971. The brand has captured the top retail market share<sup>1</sup> for vitamins in the U.S. During the period of the 3rd MTMP, *Nature Made* brand sales exceeded 100.0 billion yen, dramatically exceeding growth in the U.S. supplement market. Furthermore, we invested more than 200 million dollars to establish a new plant and R&D center in Ohio in order to expand production capacity and R&D capabilities in the gummy category, which is experiencing strong growth. The goal is to launch production in 2025.

In addition to its core brand *Nature Made*, Pharmavite is working to strengthen its lineup of women's health products in the supplement market, which included acquiring Uqora, Inc. in 2021 and Bonafide Health, LLC in 2023. During the period of the 4th MTMP, we plan to generate sustainable growth through aggressively investments in these next generation growth drivers.

1. Based on Pharmavite's own definition and using the 52-week general vitamin category data through December 31, 2023, as Circana reported in US MULO through Advantage service. ©2024, Information Resources Inc.

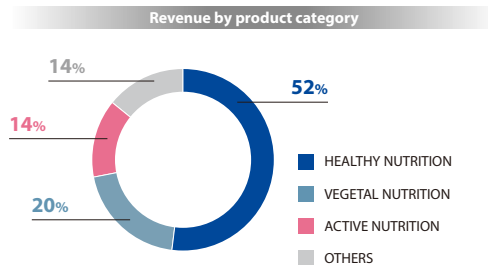
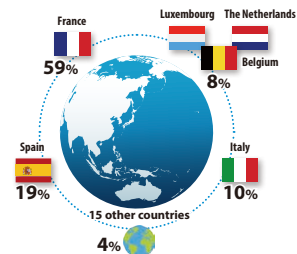
### ■ Nutrition & Santé

Expand e-commerce adapted to food service and new lifestyles

Nutrition & Santé (N&S) was founded in 1972, and is a pioneer in European health food manufacturing. "Santé" means "health" in French, so the company's objective is to provide better nutrition to keep consumers healthy. N&S has 10 factories, and offices in France, Belgium, the Netherlands, Italy, Spain, and Portugal.

During the period of the 3rd MTMP, growth in sales was flat for several reasons, including high inflation in Europe due to geopolitical conditions and business restructuring, but since the onset of the COVID-19

**Nutrition & Santé S.A. Overseas Sales Regions and Sales Share**



### Nutrition & Santé brands

HEALTHY NUTRITION	VEGETAL NUTRITION	ACTIVE NUTRITION

pandemic, we have steadily moved forward with creating a foundation for growth through such initiatives as expanding e-commerce to meet the new lifestyles of people.

### ■ EQUELLE

Taking on the challenge of a new field: women's health

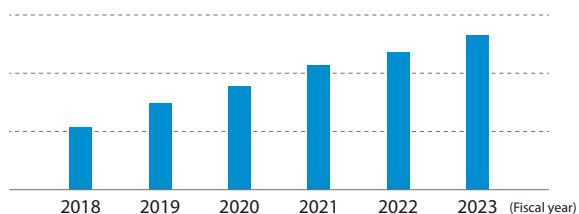
*EQUELLE* originated from research conducted at Otsuka Pharmaceuticals' Saga Nutraceuticals Research Institute, where women's health is a research theme. *EQUELLE*, which contains equol, is sold in Japan and the U.S. as a food product that supports women's health and beauty at a time when aging brings 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 their quality of life. Otsuka Pharmaceutical also provides a broad range of up-to-date information concerning women's health, including through the Women's Healthcare Project website.

During the period of the 3rd MTMP, the number of e-commerce subscription-type contracts steadily grew and sales rose dramatically as product recognition increased due to extensive provision of information, including the holding of women's health seminars. In 2021, we introduced *tocoelle*, which offers gentle support for women dealing with premenstrual changes, as a product to help women's health.

We aim to improve literacy regarding women's health and contribute to the creation of a society in which all women can energetically participate by providing both products and information based on scientific evidence.

## Business Strategy ■ Nutraceutical Business

### EQUELLE sales\*



\* Source: company material



### 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

#### Plant-based cheese and pizza, mainly in North America

Daiya Foods, a North American developer, manufacturer, and marketer of plant-based foods, develops high-quality, creative products, such as cheese substitutes, dressings, and desserts made from plant-based ingredients. The company's products are widely supported not only by vegetarians and those with food allergies, but also by health-conscious people, especially millennials.

During the period of the 3rd MTMP, we were unable to generate growth that was as strong as expected because growth in the North American market for cheese with milk substitutes slowed and competition grew fiercer. However, during the period of the 4th MTMP, we will take on the challenge of becoming the category leader for plant-based food products by generating growth of at least 10% (CAGR), which exceeds market growth, through several initiatives. We will offer a flavor that is no different than that of traditional cheese through proprietary fermentation technology and establish a product lineup to meet the needs of consumers.



## Creating innovative products to realize a future society that values well-being

### Social impact of EQUELLE on women's health issues

When EQUELLE was developed, it was thought only natural that women would have to put up with menopause symptoms. However, because many menopause symptoms are issues that normally occur, not ones due to illness, product development is driven by the idea of contributions possible from foods, not pharmaceuticals.

EQUELLE is a food product with guaranteed effectiveness and safety developed through an approach that only Otsuka, a pharmaceutical company, can employ. In addition, it was possible to raise awareness of menopausal disorders by having medical professionals provide consumers with proper information and propose EQUELLE.

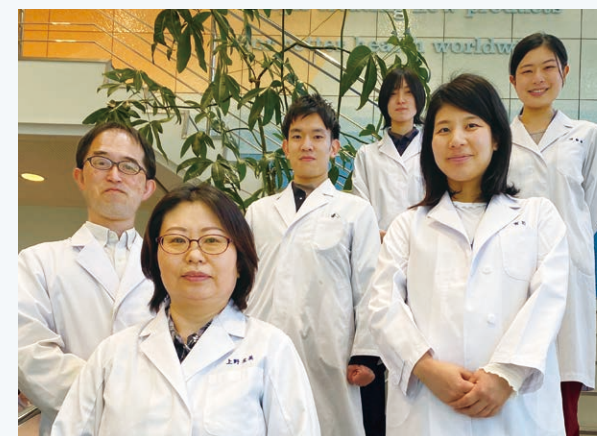
According to the Ministry of Economy, Trade and Industry, women's health problems result in an economic loss of about 3.4 trillion yen

annually for the whole of society. In response to this social issue, we will continue to undertake educational activities so that women themselves can proactively respond through such steps as seeing their gynecologist. This will be accomplished by raising awareness of menopause and premenstrual symptoms and increasing understanding among women.

During women's lives, there are other concerns that they are simply expected to tolerate. I want to continue to contribute to the creation of a society in which women proactively undertake self-care by broadening the use of Otsuka group products and proposing new products.

Tomomi Ueno (front left)

Otsuka Pharmaceutical Saga Nutraceuticals Research Institute, Director





Contribute to the Health and Well-being of People Around the World

<https://www.otsuka.com/en/rd/business/nutraceuticals/>

Please see p. 84



## Nutraceutical Business—Initiatives for Yet-To-Be-Imagined Needs

### Basic Policy

The advance of medical technology and improvement in public health has seen the average lifespan increase worldwide. However, along with decreasing birthrates and an aging population, new health challenges have emerged such as lifestyle-related diseases. These new challenges also include issues related to women's health, such as symptoms associated with menstruation and menopause. According to an estimation by Japan's Ministry of Economy, Trade and Industry published in 2024, the economic loss to society at large caused by these women-specific conditions is equivalent to 3.4 trillion yen.

At Otsuka Pharmaceutical, we consider it important that women themselves and the people around them understand the physical and mental changes women undergo during each life stage, that women select the treatment method appropriate for them, and that an appropriate environment is created so that women can play an active role. Therefore, we are committed to addressing women's health issues with a heightened focus through various means, leveraging the knowledge we have gained over many years of research and development.

### Building Awareness of Women's Health

Since 2015, we have held Women's Health Seminars throughout Japan. Furthermore, through the Otsuka Advanced Training for Healthy Aging Supporters (OATHAS) program for pharmacies and pharmacists who support the health of their local communities, we provide not only the knowledge necessary to provide that support but also opportunities to acquire practical skills. Our website includes informational pages on our Women's Health Promotion Project, KONENKI. Lab, and PMS LABORATORY, through which we offer day-to-day health support for women of all ages.

Otsuka Pharmaceutical health insurance association has offered a women's health consultation service provided by an occupational gynecologist since 2022. In addition, to create a more comfortable working environment for women, the Otsuka Pharmaceutical health insurance association holds women's health seminars that are also open to male employees.



Women's Healthcare Project

[https://www.otsuka.co.jp/woman\\_healthcare\\_project/](https://www.otsuka.co.jp/woman_healthcare_project/)

Women's health seminar

### U.S.-Based Pharmavite—Expanding Health Food Business for Women

In November 2023, Otsuka Pharmaceutical's U.S. subsidiary Pharmavite acquired Bonafide Health, LLC, which manufactures and sells women's health products. Bonafide Health was established in 2017 with the mission to "provide innovative safe and effective options that contribute to women's health." In addition to conducting R&D on, manufacturing, and selling new women's health products based on ideas gleaned from nature, we are supported by medical experts as our products are based on scientific evidence. Bonafide Health stresses providing long-term and sustainable support that meets women's health needs, which become more complex as they age, through our products.

By acquiring Bonafide Health, Pharmavite will expand its existing women's health food business, which includes Uqora, a company that specializes in the field of women's urinary track health, and *EQUELLE*, a supplements that incorporates equol.

The Otsuka group will tackle women's health issues both in Japan and overseas through its products and health education activities.



Bonafide Health products

Uqora products

EQUELLE products



## Business Strategy



Contribute to the Health and Well-being of People Around the World

### Related SDGs



<https://www.otsuka.com/en/rd/business/consumer/>



## Consumer Products Business

### 4th Medium-Term Management Plan Initiatives

- Revenue improvement & brand establishment

### FY2023 Performance

Revenue: 37.1 billion yen

Business profit: 18.1 billion yen

### Consumer Products Business Overview and Business Field

Otsuka Foods, the core of the Consumer Products Business, conducts business in the foods and beverages areas based on the topics of deliciousness, safety, peace of mind and better health by developing products that are ahead of their time, including *Bon Curry*, the world's first commercially available food in plastic pouch bags (retort bags) that was introduced in 1968.

We will use our unique ideas and development capabilities to continue to create products that are needed by the world, and contribute to the diversifying needs of our customers and solve various issues through the dinner table.

### Summary of the 3rd Medium-Term Management Plan and Outline of the 4th Medium-Term Management Plan

During the period of the 3rd Medium-Term Management Plan (MTMP), *MATCH* sales fell slightly in both 2020 and 2021 for various reasons, including restrictions on people going out due to the COVID-19 pandemic. Since 2022, when consumer activity began to recover, sales have increased for two consecutive years as a result of stronger marketing to young people, our main target. Sales of *Bon Curry* rose dramatically due to greater demand as people were stuck at home during the COVID-19 pandemic and aggressive marketing activities, such as launching the first new products (Gold and NEO series) in 6 years in 2023. Through the 4th MTMP, we aim to increase sales by undertaking effective marketing activities, particularly for beverages and retort-pouch products, the core of the business.

### Major Products

Launched in 1996, *MATCH* is a vitamin-enhanced carbonated beverage that is easy to gulp down because of its refreshing flavor and light carbonation, making it possible to get vitamins and minerals in a delicious manner. *Bon Curry* was created as the world's first commercially available retort pouch food

based on the concept of "one serving of curry that can be prepared just by heating it in hot water, a fool proof way of cooking curry" and created using innovative unique technology.

*MY SIZE* is a series of 100 kcal retort pouch foods developed based on the concept that "meals should also come in small sizes." The series features easy-to-understand calorie labels, a salt content of no more than 2 g, a full lineup with a wide range of menu items, a rich, full-bodied flavor, and easy preparation in a microwave oven, and is used by many people for daily diet management.



### Creating innovative products and link that to future wellbeing society

#### Contributing to well-being through *MY SIZE*

*MY SIZE* is a series of products for people who want to enjoy, not sacrifice, food in order to maintain their health that is based on the concept of selecting meals of the appropriate size for oneself. During development, one aspect we struggled with was not compromising flavor while limiting the calorie content for the popular curry and rice-bowl topping to no more than 100 kcal. In response to customer opinion, we also evolved the design in 2016 to lower the salt content for all products to no more than 2 g.

Retort pouch foods are growing more diverse as they are not only no longer simply convenient and fulfill a role as disaster rations but also now meet needs related to flavor, individual meals, and easy meals for two-income households. Through product development from a "food and health" perspective, we will provide delicious products that respond to consumer opinions by proposing new retort pouch meal and evolving our technology.



**Koji Eto**  
Assistant Director  
Biwako Research Institute  
Otsuka Foods Co., Ltd.

## Business Strategy



Contribute to the Health and Well-being of People Around the World

### Related SDGs



<https://www.otsuka.com/en/rd/business/others/>



## Other Businesses

### 4th Medium-Term Management Plan Initiatives

- Developing new markets both in Japan and overseas that support long-term growth

#### Otsuka Chemical

- Reinforcing global system (business expansion and local production)
- Pharmaceutical CDMO<sup>1</sup> business that leverages proprietary technology

1. CDMO: Contract Development and Manufacturing Organization

#### Otsuka Warehouse

- Promoting greater logistics efficiency through use of common platform with partner companies
- Promoting digitalization of delivery operations

### FY2023 Results

Revenue: 107.0 billion yen

Business profit: 3.1 billion yen

## Business Outline and Business Field

Otsuka's diversified operations include a chemical business that supplies various materials in the fields of automobiles, electrical and electronic equipment, and construction; a transportation and warehousing business that aims for environmentally friendly logistics, mainly for Otsuka group pharmaceuticals, foods, and beverages; and an electronic equipment business that supports the development of leading-edge technologies.

### Otsuka Chemical

With materials at the core, Otsuka Chemical is engaged in the development of a wide variety of value-added materials that meet the needs of the automotive, electrical and electronics, housing, and pharmaceutical industries. Through the 3rd Medium-Term Management Plan (MTMP), we aimed to strengthen both our in-house material and technologies by area. In our Films Business, which provides products for automobiles, smartphones, and similar products, we launched operation of a process development building, expanded our lineup of anti-reflective films, and developed high value-added products through the combination of technologies we have developed. As for pharmaceutical raw materials, we deepened collaboration with customers and partner companies through open innovation by opening the Shonan Laboratory, and in May 2023, we started to supply CDMO services for medium-molecule drugs using the continuous flow synthesis method.

Through the 4th MTMP, we will use our strength of possessing an extensive line-up of unique products, primarily for growth markets, including semiconductors, mobility, and medium-molecule drug markets, to propose solutions for such activities as



SynCrest Inc., a joint venture with Yokogawa Electric Corporation (a plant for the manufacture of bulk pharmaceuticals for medium-molecule drugs)

product development and manufacturing method improvements to lessen the environmental load, through decarbonization for example.

### Otsuka Warehouse

Otsuka Warehouse is a unique pharmaceutical manufacturer logistics company that promotes collaboration with other manufacturers, particular related to the Otsuka group's pharmaceuticals, beverages and food products, and daily necessities. We are building a connected logistics systems by leveraging technology and introducing IT into delivery operations and warehousing operations. Through these efforts, we not only achieve efficient logistics processes but also provide value-added logistic solutions that reduce environmental load and resolve the problem of insufficient shipping capacity.

Actual shipping volume per year (Japan): **170** million units

Actual destinations delivered to per year: **22,000**

Logistics sites in Japan: **83**

Number of types of products handled: **12,000**

### Otsuka Electronics

Otsuka Electronics conducts business in three categories based on technology that uses light as a medium. These three categories are medical testing devices, analytical devices and spectrometers. In the medical testing field, our medical testing devices include POCConePlus, clinical test devices that test for Helicobacter pylori. In the analytical field, our analytical devices include Zeta-Potential and NanoParticle Size measurement instruments. And in the spectrometry field, our spectrometers include inspection instruments, such as contact-free thickness meters, for the semiconductor, functional materials and film materials industries. We always aim to create state-of-the-art technology and to fulfill customer needs in each business field, enabling the development of products that support daily life based on our business-to-business strategy. Otsuka Electronics continuously develops high-added-value products to solve problems, working together with customers.

# R&D to Support Our Business

## Our R&D Organization

Fiscal 2023 Results

**Pharmaceutical Business R&D Expenses**

**292.0 billion yen**

Fiscal 2023 Results

**In-House Drug Discovery Ratio<sup>1</sup>**

**68%**

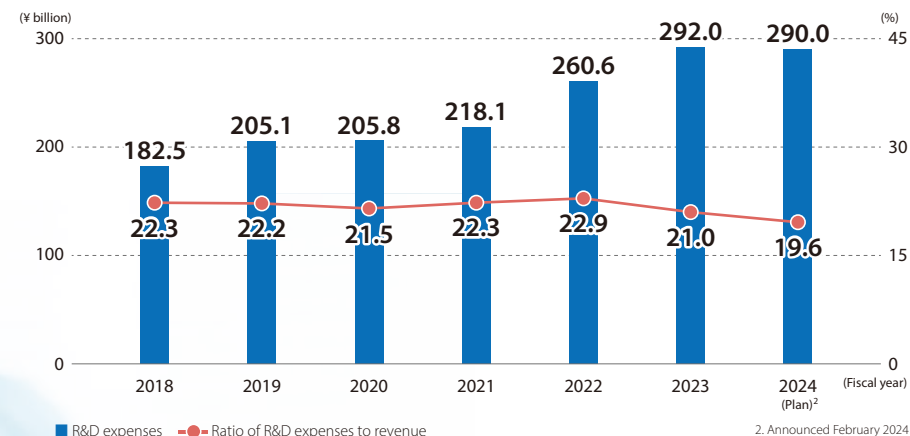
1. Among late-stage development projects (Phase 3 and beyond) percentage of Otsuka drugs discovered in-house

Fiscal 2023 Results

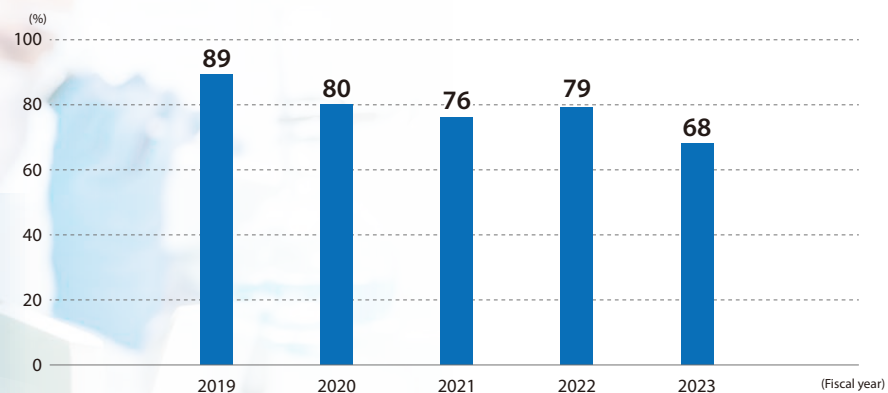
**Pharmaceutical Business Ratio of R&D expenses to revenue**

**21.0%**

Pharmaceutical Business R&D Expenses and Ratio of R&D Expenses to Revenue



Percentage of in-house drug discovery<sup>1</sup>



In order to research and develop innovative products that contribute to curing diseases and support good health, the Otsuka group has established a network of domestic and overseas group research institutes and is engaged in diverse drug discovery research under a global structure.

The Otsuka group's strength lies in its unique and diverse research base, and it will organically integrate its drug discovery research base, mainly small molecules accumulated through years of new drug research, with cutting-edge technologies to create innovation through a value creation process based on *Ryukan-godo*, *Jissho*, and *Sozosei*.

## R&D to Support Our Business

### Representative Research Institutes for the Pharmaceutical Business

#### 1 Astex

Astex Pharmaceuticals, which conducts fragment-based drug discovery of small molecule compounds for oncology and psychiatric and neurological disorders, has created anti-cancer drugs such as *Kisqali*,<sup>1</sup> *Balversa*,<sup>2</sup> *INQOVI*, and *Truqap*.<sup>3</sup> Furthermore, in addition to drug design based on protein structure analysis using cryo-electron microscopy, Astex Pharmaceuticals is working to create innovative drugs through target and mechanism analysis using quantum computers.

1. Product sold by Novartis  
2. Product sold by Janssen Biotech  
3. Product sold by AstraZeneca



#### 2 Tokushima Research Center for Drug Discovery, Otsuka Pharmaceutical

The Tokushima Research Center for Drug Discovery has provided new therapeutic agents such as *REXULTI* and *Samsca/JINARC/JYNARQUE* for psychiatric and neurological diseases and cardiovascular and renal diseases. To fulfill unmet needs, we continue to conduct research activities focusing on drug discovery approaches with small molecules, both phenotypic drug discovery and targeted drug discovery, utilizing the experience we have accumulated over the years. Furthermore, we are expanding our drug discovery capabilities through collaboration with the Osaka Research Center for Drug Discovery and the use of new technologies. We also conduct safety and pharmacokinetic studies to advance our products to clinical trials (investigational new drugs).



#### 3 Osaka Research Center for Drug Discovery, Otsuka Pharmaceutical

In addition to carrying on Otsuka Pharmaceutical's drug discover history and culture, the Osaka Research Center for Drug Discovery generates new innovation. Having built a network with research institutes and biotech companies both in Japan and overseas, we are engaged in drug discovery research for small molecule compounds and biologics. Equipped with cutting edge research equipment, including one of the world's most advanced cryo-electron microscopes and automated organoids culture equipment, we are undertaking new drug discovery, including that which incorporates cutting-edge immunology and digital transformation.



#### 4 Discovery and Preclinical Research Division (Tsukuba Area), Taiho Pharmaceutical

In the Tsukuba Area, Taiho Pharmaceutical's Discovery and Preclinical Research Division is taking on the challenge of discovering new original drug candidate compounds that indicate outstanding efficacy and high safety, mainly in the fields of oncology and immunology. In addition to our proprietary drug discovery platforms, such as the Cysteinomix Drug Discovery Platform and the RAS Drug Discovery Platform, which led to the discovery of futibatinib and zipalertinib (TAS6417), we are actively working to improve and expand our drug discovery platform technologies, including the introduction of robotics technology to increase and accelerate research productivity and the use of artificial intelligence (AI) in the search for drug targets and compound design.



#### 5 Visterra

Leveraging its strength with antibodies and biologics, Visterra is undertaking R&D in the fields of immune-mediated and renal diseases where current treatment options are limited. We are steadily making progress with clinical trials, including a Phase 3 study of sibeprenlimab (VIS649) and a Phase 1 study of VIS171.

Our proprietary technology Hierotope® platform makes it possible to design antibody drugs for many biological substances by calculating and predicting the protein-antibody binding. As part of Otsuka Pharmaceutical's Open Innovation Strategy, we are collaborating with universities and hospitals in and around Boston.



# Product Development Pipelines

At least in Phase 3 as of December 31, 2023

Category	Brand name (Generic name) Development Code	Indication / Dosage form	Development status						
			JP		U.S.		EU		
			Phase 3	Filed	Phase 3	Filed	Phase 3	Filed	Approved
Psychiatry and neurology area	<b>REXULTI/RXULTI (brexpiprazole) OPC-34712 / OPC-34712 FUM</b>	Agitation associated with dementia due to Alzheimer's disease / Oral		●					
		Posttraumatic stress disorder / Oral				●			
		Schizophrenia / Once-weekly oral	●						
	<b>(aripiprazole 2-month long-acting injection)</b>	Schizophrenia / Depot injection							● <sup>1</sup>
	<b>(centanafadine) EB-1020</b>	Attention-deficit hyperactivity disorder / Oral			●				
	<b>(ulotaront) SEP-363856</b>	Schizophrenia / Oral	● <sup>2</sup>		●				
		Major depressive disorder / Oral			● <sup>2</sup>				
		Generalized anxiety disorder / Oral	● <sup>2</sup>		● <sup>2</sup>				
<b>(pizuglanstat) TAS-205</b>	Duchenne muscular dystrophy / Oral	●							
Oncology area	<b>INAQOVI (decitabine, cedazuridine) ASTX727</b>	Myelodysplastic syndromes / Oral							●
	<b>(pamufetinib) TAS-115</b>	Osteosarcoma / Oral	●						
	<b>(zipalertinib) TAS6417</b>	Non-small cell lung cancer / Oral	●		●		●		
	<b>(zimberelimab + domvanalimab) AB122 + AB154</b>	Upper gastrointestinal tract cancer / Injection	●						
Cardiovascular and renal areas	<b>(sibeprenlimab) VIS649</b>	IgA nephropathy / Injection	●		●		●		
	<b>(bempedoic acid) ETC-1002</b>	Hypercholesterolemia / Oral	●						
	<b>(voclosporin)</b>	Lupus nephritis / Oral		●					
Other categories	<b>Deltyba (delamanid) OPC-67683</b>	Multidrug-resistant tuberculosis / Oral			●				
	<b>(glucose, electrolyte, amino acid and vitamin) OPF-109</b>	High-calorie parenteral nutrition for chronic renal failure / Injection		●					

1. Approved in March 2024

2. Phase 2/3

# Research and Development Activities

At least in Phase 2 as of December 31, 2023

Category	Brand name (Generic name) Development Code	Area	Treatment / Indication	Status
Psychiatry and neurology area	<b>REXULTI (brexpiprazole) OPC-34712 / OPC-34712 FUM</b>	Japan	Major depressive disorder	New indication added in December 2023
		Japan	Agitation associated with dementia due to Alzheimer's disease	Application filed in October 2023
		U.S.	Agitation associated with dementia due to Alzheimer's disease	New indication added in May 2023
	<b>ABILIFY ASIMTUFII (aripiprazole 2-month long-acting injection)</b>	U.S.	Schizophrenia, bipolar I disorder	Approval granted in April 2023
Oncology area	<b>INAQOVI (decitabine, cedazuridine) ASTX727</b>	Europe	Myelodysplastic syndromes	Application filed in December 2023
		Europe	Acute myeloid leukemia	Approval granted in September 2023
	<b>Jeselhy (pimipitespib) TAS-116</b>	Japan	Prostate cancer	Start of Phase 2 trial in September 2023
	<b>LYTGOBI (futibatinib) TAS-120</b>	Japan	Bile duct cancer	Approval granted in June 2023
	<b>LYTGOBI (futibatinib) TAS-120</b>	Europe	Cholangiocarcinoma	Approval granted in July 2023
	<b>TAS3351</b>	Japan, U.S. and Europe	Non-small cell lung cancer	Start of Phase 1/2 trial in June 2023
	<b>(zipalertinib) TAS6417</b>	Japan, U.S. and Europe	Non-small cell lung cancer	Start of Phase 3 trial in December 2023
	<b>(zimberelimab + domvanalimab) AB122 + AB154</b>	Japan	Upper gastrointestinal tract cancer	Start of Phase 3 trial in June 2023
<b>OPF-501C</b>	Japan	Cancerous skin ulcers	Start of Phase 2 trial in July 2023	
Cardiovascular and renal areas	<b>OPC-131461</b>	Japan	Cardiac edema	Start of Phase 2 trial in January 2023
	<b>(bempedoic acid) ETC-1002</b>	Japan	Hypercholesterolemia	Start of Phase 3 trial in February 2023
	<b>(voclosporin)</b>	Japan	Lupus nephritis	Application filed in November 2023
Other categories	<b>(glucose, electrolyte, amino acid and vitamin) OPF-109</b>	Japan	High-calorie parenteral nutrition for chronic renal failure	Application filed

\* The above description of status in U.S. and Europe; "Application filed," indicates that an application for approval has been submitted to or accepted by the relevant authorities. For other countries and regions, it indicates that an application for approval has been submitted to the relevant authorities.