

## Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending December 31, 2023 [IFRS]

October 31, 2023

Company name	: <b>Otsuka Holdings Co., Ltd.</b>
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
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Scheduled date of quarterly securities report submission	: October 31, 2023
Scheduled date of dividend payment commencement	: –
Supplementary materials for quarterly financial results	: Yes
Earnings announcement for quarterly financial results	: Yes (for institutional investors, analysts and the press)

(Figures are rounded down to the nearest million unless otherwise stated)

### 1. Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending December 31, 2023 (January 1, 2023 to September 30, 2023)

#### (1) Consolidated Operating Results (cumulative)

(% indicates percentage of change from the same period of the previous fiscal year)

	Revenue		Business profit		Operating profit		Profit for the period		Profit attributable to owners of the Company		Total comprehensive income for the period	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
FY2023 Q3	1,479,080	16.8	258,483	105.6	202,650	76.5	165,313	45.1	161,713	45.6	316,787	(8.0)
FY2022 Q3	1,266,119	14.3	125,694	(19.4)	114,848	(27.4)	113,950	(12.4)	111,036	(12.3)	344,362	81.6

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY2023 Q3	297.99	297.99
FY2022 Q3	204.66	204.64

\*1 Business profit is an indicator of ordinary earnings power calculated as follows:

Revenue – Cost of sales – Selling, general and administrative expenses – Research and development expenses + Share of profit of investments accounted for using the equity method

\*2 Due to the application of IAS 12 “Income Taxes” (amended in May 2021), results for the nine-month period ended September 30, 2022, have been retrospectively restated.

\*3 There is no dilution in basic earnings per share for the nine-month period ended September 30, 2023.

#### (2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity attributable to owners of the Company per share
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of September 30, 2023	3,417,971	2,525,788	2,483,046	72.6	4,575.47
As of December 31, 2022	3,102,638	2,262,369	2,225,255	71.7	4,100.84

\* Due to the application of IAS 12 “Income Taxes” (amended in May 2021), figures as of December 31, 2022, have been retrospectively restated.

### 2. Dividends

	Annual dividend per share				
	First Quarter end	Second Quarter end	Third Quarter end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
FY2022	–	50.00	–	50.00	100.00
FY2023	–	50.00	–	–	–
FY2023 (forecast)	–	–	–	50.00	100.00

\* Revisions to dividends forecast most recently announced: None

**3. Forecast of Consolidated Financial Results for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)**  
(% indicates percentage of change from the same period of the previous fiscal year)

	Revenue		Business profit		Operating profit		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
FY2023	1,985,000	14.2	300,000	71.5	245,000	63.0	192,000	39.9	188,000	40.4	346.44

\*1 Revisions to financial forecast most recently announced: Yes

\*2 Due to the application of IAS 12 "Income Taxes" (amended in May 2021), the percentage of change from the same period of the previous fiscal year has been calculated using retrospectively restated figures.

**4. Others**

(1) Changes in significant subsidiaries during the nine-month period ended September 30, 2023 (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates

- 1) Changes in accounting policies required by IFRS: Yes
- 2) Changes in accounting policies due to other reasons: None
- 3) Changes in accounting estimates: None

\* Please refer to "2. Condensed Interim Consolidated Financial Statements and Major Notes (6) Notes to Condensed Interim Consolidated Financial Statements (Changes in Accounting Policies)" for details.

(3) Number of shares issued and outstanding (common stock)

- 1) Number of shares issued and outstanding as of the end of the reporting period (including treasury shares):
 

September 30, 2023	557,835,617 shares
December 31, 2022	557,835,617 shares
- 2) Number of shares of treasury shares as of the end of the reporting period:
 

September 30, 2023	15,149,580 shares
December 31, 2022	15,201,916 shares
- 3) Average number of shares outstanding during the reporting period:
 

Nine-month period ended September 30, 2023	542,662,437 shares
Nine-month period ended September 30, 2022	542,530,099 shares

\* This report is out of scope of reviews by the external auditor.

**\* Note to ensure appropriate use of forecasts, and other comments in particular**

Forecasts and other forward-looking statements included in this report are based on information currently available and certain assumptions that Otsuka Holdings Co., Ltd. (hereinafter referred to as the "Company") deems reasonable. Actual performance and other results may differ significantly due to various factors. Please refer to "1. Qualitative Information (3) Forecast for Consolidated Financial Results" on page 10 for details with regard to the assumptions and other matters concerning the financial forecast.

The Company plans to hold a conference call for institutional investors, analysts and the press on October 31, 2023. Presentation materials and the webcast of the call will be available on the Company's website promptly after the call.

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## 1. Qualitative Information

From the three-month period ended March 31, 2023, IAS 12 “Income Taxes” (amended in May 2021) has been applied and comparative analysis with the nine-month period ended September 30, 2022 and the previous fiscal year-end has been made using retrospectively restated figures. The application of this standard did not have a material impact on Condensed Interim Consolidated Financial Statements. The details of the changes in accounting policies are stated in “(6) Notes to Condensed Interim Consolidated Financial Statements (Changes in Accounting Policies)” in “2. Condensed Interim Consolidated Financial Statements and Major Notes.”

### (1) Consolidated Operating Results

The forward-looking statements in this report were prepared based on information available as of September 30, 2023.

#### Summary of consolidated financial results for the nine-month period ended September 30, 2023

The Company and its affiliated companies (hereinafter referred to as the “Group”) adopted “Business profit” as an indicator of ordinary earnings power, which is calculated as follows:

Revenue – Cost of sales – Selling, general and administrative expenses – Research and development expenses + Share of profit of investments accounted for using the equity method

(Millions of yen)

	Nine-month period ended September 30, 2022	Nine-month period ended September 30, 2023	Change	% Change
Revenue	1,266,119	1,479,080	212,961	16.8 %
Business profit before research and development expenses	319,460	474,120	154,660	48.4 %
Business profit	125,694	258,483	132,789	105.6 %
Operating profit	114,848	202,650	87,802	76.5 %
Profit before tax	145,999	213,208	67,208	46.0 %
Profit for the period	113,950	165,313	51,362	45.1 %
Profit attributable to owners of the Company	111,036	161,713	50,677	45.6 %
Research and development expenses	193,765	215,637	21,871	11.3 %
Impairment losses	30,697	57,172	26,474	86.2 %

Based on the concept of total health care, the Group has been operating its businesses to maintain and promote health and to diagnose and treat disease. Amid a changing social environment, to anticipate social issues brought about by a highly uncertain world, the Group will incorporate new technologies and needs arising from changes in the environment and harness the opportunities presented by a growing awareness of health in order to demonstrate the Group’s true value as a total healthcare company, especially now, and continue to move toward the realization of sustainable growth.

Revenue for the nine-month period ended September 30, 2023 totaled ¥1,479,080 million (up 16.8% over the same period of the previous fiscal year), as all operating segments recorded increased revenue. The main factors were that growth in sales for the four global products, the long acting antipsychotic agent *ABILIFY MAINTENA*, the antipsychotic agent *REXULTI*, the V<sub>2</sub>-receptor antagonist *JYNARQUE*, and the anti-cancer agent *LONSURF*, in addition to growth in royalties and milestones for out-licensed products, drove results in the pharmaceutical business. As a result, revenue grew significantly, exceeding the decline in revenue with the expiry of the exclusive sales period of the V<sub>2</sub>-receptor antagonist *Samsca* for the treatment for fluid retention in patients with heart failure and hepatic cirrhosis in Japan. Furthermore, in the nutraceutical business as well, sales of *POCARI SWEAT* and *Nature Made* continued to grow amid increasing health awareness.

Business profit before research and development expenses was ¥474,120 million (up 48.4%). The main factors were as follows. On one hand, the gross profit increased due to high sales for the four global products, and increased royalties and milestones for out-licensed products. On the other hand, amid efforts to accelerate investment in new businesses, the SG&A expense ratio was reduced by appropriately controlling selling, general and administrative expenses through efficient investment in existing businesses.

Research and development expenses totaled ¥215,637 million (up 11.3%) mainly due to development expenses based on a collaboration and license agreement executed with Sumitomo Pharma Co., Ltd. for joint development and commercialization related to antipsychotic agent with a novel mechanism of action, as well as due to steady progress for zipalertinib/TAS6417 under development for the treatment of non-small cell lung cancer and sibeprenlimab/VIS649 which is under development for the treatment of IgA nephropathy. There was also the impact of exchange rate fluctuations.

As a result of greater than anticipated sales growth and appropriate controls having been imposed on selling, general and administrative expenses, business profit increased significantly to ¥258,483 million (up 105.6%).

Operating profit increased to ¥202,650 million (up 76.5%). This can be attributed to the greater than anticipated growth in revenue, despite the recording of impairment losses in relation to Daiya Foods Inc., collaboration with Sumitomo Pharma Co., Ltd., etc.

Furthermore, profit for the period was ¥165,313 million (up 45.1%), and profit attributable to owners of the Company was ¥161,713 million (up 45.6%).

Revenue and business profit by business segment during FY2023 Q3

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	992,416	359,126	28,453	131,936	(32,851)	1,479,080
Business profit	222,017	51,493	14,148	8,670	(37,847)	258,483

Reference (FY2022 Q3)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	819,334	325,631	27,006	126,099	(31,952)	1,266,119
Business profit	101,346	46,299	5,842	7,398	(35,192)	125,694

1) Pharmaceuticals

Revenue for the nine-month period ended September 30, 2023 totaled ¥992,416 million (up 21.1%), with business profit of ¥222,017 million (up 119.1%).

**Main products**

● Four global products

The Group positions the long acting antipsychotic agent *ABILIFY MAINTENA*, the antipsychotic agent *REXULTI*<sup>1</sup>/*RXULTI*<sup>2</sup>, the V<sub>2</sub>-receptor antagonist *Samsca*/*JINARC*<sup>3</sup>/*JYNARQUE*<sup>4</sup> and the anti-cancer agent *LONSURF* as its four global products. Sales of those products totaled ¥527,977 million (up 16.2%).

\*1: Brand name for the antipsychotic agent outside Europe

\*2: Brand name for the antipsychotic agent in Europe

\*3: Brand name for autosomal dominant polycystic kidney disease (“ADPKD”) treatment in multiple regions outside Japan

\*4: Brand name for ADPKD treatment in the U.S.

• Long acting antipsychotic agent *ABILIFY MAINTENA*

In the U.S., sales increased atop growth in prescriptions, mainly due to promoting the efficacy of the product for bipolar I disorder and schizophrenia patients, who have problems adhering to drug regimens, as well as face-to-face detailing activities, and the impact of exchange rate fluctuations. In Japan, sales grew steadily due to stronger information provision activities for bipolar I disorder, in addition to schizophrenia. As a result, sales of *ABILIFY MAINTENA* totaled ¥147,146 million (up 22.2%).

• Antipsychotic agent *REXULTI/RXULTI*

In the U.S., the drug is sold as adjunctive therapy in major depressive disorder, as a treatment for schizophrenia, and from May 2023, as a treatment for agitation associated with dementia due to Alzheimer’s disease. Prescriptions grew and sales increased, mainly due to enhancement of face-to-face detailing activities, as well as the impact of exchange rate fluctuations in the country. The Group is actively engaged in activities to raise awareness of agitation associated with dementia due to Alzheimer’s disease and is also conducting DTC<sup>\*5</sup> advertising. In Japan, sales increased, boosted by new prescriptions due to enhancement of detailing activities for schizophrenia. As a result, sales of *REXULTI/RXULTI* totaled ¥153,098 million (up 26.0%).

\*5: Direct to consumer

• V<sub>2</sub>-receptor antagonist *Samsca*

In Japan, the number of prescriptions for autosomal dominant polycystic kidney disease (“ADPKD”) increased, and the number of patients who have received treatment has exceeded 10,000 cases. On the other hand, sales significantly decreased due to the impact of the launch of generics for the treatment for fluid retention in patients with heart failure and hepatic cirrhosis. Also in the U.S., where the drug is sold as a treatment for hyponatremia, sales significantly decreased due to the impact of the launch of generics. As a result, sales of *Samsca* totaled ¥36,928 million (down 47.8%).

• V<sub>2</sub>-receptor antagonist *JINARC/JYNARQUE*

In the U.S., sales increased significantly as a result of an increase in the number of prescriptions for ADPKD mainly due to continued efforts to raise awareness of the disease and provision of information about clinical data, as well as the impact of exchange rate fluctuations. As a result, sales of *JINARC/JYNARQUE* totaled ¥132,853 million (up 32.9%).

• Anti-cancer agent *LONSURF*

In the U.S., sales increased significantly due to the approval in August 2023 for the additional indication for treatment in combination with bevacizumab for colorectal cancer, the recommendation of the combination therapy in NCCN Guidelines<sup>\*6</sup> and the impact of exchange rate fluctuations. In Europe, sales increased significantly due to the increase in the number of prescriptions and the impact of exchange rate fluctuations. In addition, the combination therapy was approved in July 2023. In Japan, prescriptions continued to be solid due to increased awareness of the combination therapy following

the publication of a research paper, etc. As a result, sales of *LONSURF* totaled ¥57,949 million (up 38.1%).

\*6: Cancer treatment guidelines that are used widely around the world

## 2) Nutraceuticals

Revenue for the nine-month period ended September 30, 2023 totaled ¥359,126 million (up 10.3%), with business profit of ¥51,493 million (up 11.2%).

### Main products

The Group positions *POCARI SWEAT*, *Nature Made* and the Nutrition & Santé SAS brand as its three major brands. Sales of those brands totaled ¥234,607 million (up 15.7%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥20,621 million (down 2.6%).

#### ● Three major brands

Sales volume of *POCARI SWEAT*, an electrolyte supplement drink, decreased temporarily due to the impact of the price revision in April 2023 in Japan. However, sales volume was steadily increasing during the summer this year, which had the highest temperatures on record<sup>\*7</sup>, due to the promotion of consumption accompanying rising interest in measures for heat disorder in daily life and an increase in brand contact points and drinking experiences at sports events, and other factors as a result of our continuing education about hydration and replenishment of electrolytes. Overseas, more people have been recognizing the importance of hydration and replenishment of electrolytes through activities to raise awareness that are tailored to the culture and situation in each region. Through the building of a brand image through many years of initiatives, sales volume is steadily increasing. As a result, sales volume increased overall for the brand, leading to an increase in sales.

Sales of *Nature Made* supplements by Pharmavite LLC increased due to an expanded market share<sup>\*8</sup> in the U.S. backed by enhanced awareness of physical conditioning among consumers and their high trust in the brand and quality, and also boosted by marketing activities through social media and the impact of exchange rate fluctuations.

The Nutrition & Santé SAS brand, which sells health food products mainly in Europe, is expanding its food services<sup>\*9</sup> and e-commerce. Although there was a one-time sales decline due to the impact of business reorganization, Japanese yen-based sales increased mainly due to growth in the main products such as *Gerblé* and the impact of the exchange rate fluctuations.

\*7: Japan Meteorological Agency: The average temperatures during the summer (June to August) throughout Japan were the highest since recordkeeping began in 1898.

\*8: IRI Data: Market Advantage; Calendar YTD 9/10/2023, Food, Drug, Mass Excluding Amazon and Costco

\*9: Services for providing meals to public institutions, schools, etc.

#### ● Three nurture brands

Plant-based foods of the Daiya Foods Inc. brand saw a decrease in sales, mainly due to increased competition in the dairy alternative cheese market in North America. However, efforts have been made to enhance the product lineup by utilizing its original technology and expand distribution.

Sales of *EQUELLE*, a food and supplement brand containing equol that supports women's health and beauty, continued to grow steadily in Japan due to increased recognition of the product through the wide-ranging spread of information on the product, including seminars on women's health, and due to an increase in the number of e-commerce subscriptions.

As for *BODY MAINTÉ*, a protective beverage brand containing the plant-based lactic-acid bacteria B240<sup>\*10</sup>, although sales declined, efforts were made to strengthen activities for increasing awareness of the product value, develop core users, and raise recognition and increase consumption of the product.

\*10: Lactiplantibacillus pentosus ONRICb0240: Strain isolated by Tokyo University of Agriculture, for which Otsuka Pharmaceutical has confirmed efficacy.

## 3) Consumer products

Revenue for the nine-month period ended September 30, 2023 totaled ¥28,453 million (up 5.4%), while business profit totaled ¥14,148 million (up 142.2%) in part due to an increase in share of profit of investments accounted for using the equity method.

In mineral water products, sales of mainstay brand *CRYSTAL GEYSER* increased in Japan mainly by appealing to the brand value by communicating the environmental initiatives through the use of lightweight bottles and caps and bottles made from 50% recycled raw materials, although sales volume decreased due to the impact of the price revision. Sales volume of *MATCH*, a carbonated vitamin drink, increased due to an increase in the number of users of existing products and strong sales of *MATCH Salty Lemon Soda*, which was launched in March 2023.

## 4) Others

Revenue for the nine-month period ended September 30, 2023 totaled ¥131,936 million (up 4.6%), with business profit of ¥8,670 million (up 17.2%).

Sales in the specialty chemical business decreased marginally as a result of sluggish sales of chemicals for the semiconductor industry due to stagnation in the semiconductor market, particularly the delayed recovery in the Chinese market. Sales in the fine chemical business increased mainly due to an increase in sales of antibiotic intermediates.

In the transportation and warehousing business, despite the acquisition of new external customers and steady growth in handling volume by strengthening the total healthcare distribution platform through coordination of logistics data, sales decreased marginally

due to a decline in the unit freight rates for international transportation, which had been on an upward trend.

\* Please refer to the Supplement Documents (FACT BOOK) for sales by product and other information.  
<https://www.otsuka.com/en/ir/library/materials.html>

## Research and Development Activities

Research and development expenses for the nine-month period ended September 30, 2023 totaled ¥215,637 million.

The primary areas of research and development as well as the status of new product development by segment were as follows:

### Pharmaceuticals

The Group conducts research and development with a primary focus on the areas of psychiatry and neurology, and oncology. The Group also conducts research and development focusing on fields that are yet to be fully addressed such as cardiovascular and renal system, etc.

Research and development expenses in the pharmaceutical business for the nine-month period ended September 30, 2023 were ¥204,720 million.

Research and development activities in the pharmaceutical business carried out for the nine-month period ended September 30, 2023 are summarized below.

Category	Development Code	Brand Name	Generic Name	Area	Treatment/ Indication	Status*
Psychiatry and neurology	OPC-34712	<i>REXULTI / RXULTI</i>	brexpiprazole	Japan	Major depressive disorder	An application was filed in January 2023
				U.S.	Agitation associated with Alzheimer's dementia	Granted approval as an additional indication in May 2023
				Europe	Major depressive disorder	Discontinued for business reason
					Agitation associated with Alzheimer's dementia	Discontinued for business reason
	aripiprazole long-acting injection	<i>ABILIFY MAINTENA</i>	aripiprazole	China	Schizophrenia	Granted approval in May 2023
	aripiprazole 2-month long-acting injection	<i>ABILIFY ASIMTUFII</i>		U.S.	Schizophrenia, bipolar I disorder	Granted approval in April 2023
AVP-786	—	deuterium-modified dextromethorphan, quinidine	U.S.	Negative symptoms of schizophrenia	Discontinued for strategic reason	
SEP-4199	—	—	Japan and U.S.	Bipolar I depression	Discontinued the studies due to significant delay in the recruitment progress	
Oncology	ASTX727	<i>INAQOVI</i>	decitabine, cedazuridine	Europe	Acute myeloid leukemia	Granted approval in September 2023
	ASTX660	—	tolinapant	U.S.	Solid tumors, lymphoma	Discontinued for strategic reason
	ASTX660 + ASTX727	—	tolinapant + decitabine, cedazuridine	U.S.	T-cell lymphoma	Phase I trial was initiated in February 2023
				U.S.	Acute myeloid leukemia	Discontinued for strategic reason
	AP24534	<i>ICLUSIG</i>	ponatinib	China	Chronic myeloid leukemia, acute lymphoblastic leukemia	An application was filed in March 2023
	TAS-116	<i>Jeselhy</i>	pimipespib	Japan	Prostate cancer	Phase II trial was initiated in September 2023
TAS-120	<i>LYTGOBI</i>	futibatinib	Japan	Unresectable biliary tract cancer harboring FGFR2 gene fusions that has progressed after	Granted approval in June 2023	



Category	Development Code	Brand Name	Generic Name	Area	Treatment/ Indication	Status*
					chemotherapy	
				Europe	Cholangiocarcinoma	Granted approval in July 2023
	TAS3351	—	—	Japan, U.S. and Europe	Non-small cell lung cancer	Phase I/II trial was initiated in June 2023
	TAS3681	—	—	U.S. and Europe	Prostate cancer	Discontinued for strategic reason
	TAS6417	—	zipalertinib	Japan	Non-small cell lung cancer	Phase I/II trial was initiated in July 2023
	AB122 + AB154	—	zimberelimab + domvanalimab	Japan	Upper gastrointestinal tract cancer	Phase III trial was initiated in June 2023
				Japan	Non-small cell lung cancer	Phase I trial was initiated in June 2023
	AB122 + TAS-120	—	zimberelimab + futibatinib	Japan	Solid tumors	Phase I trial was initiated in January 2023
	OPF-501C	—	zinc chloride	Japan	Cancerous skin ulcers	Phase II trial was initiated in July 2023
	OPB-171775	—	—	Japan	Solid tumors	Discontinued for strategic reason
Cardio-vascular and renal system	ETC-1002	—	bempedoic acid	Japan	Hyper-cholesterolemia	Phase III trial was initiated in February 2023
	OPC-131461	—	—	Japan	Cardiac edema	Phase II trial was initiated in January 2023
Other categories	OPA-15406	<i>Moizerto</i>	difamilast	China	Atopic dermatitis	Phase III trial was initiated in February 2023
	OPC-1085EL	<i>Mikeluna</i>	carteolol, latanoprost	China	Glaucoma, ocular hypertension	Phase III trial was initiated
	OPS-2071	—		China	Irritable bowel syndrome	Phase II trial was initiated in June 2023
	VIS171	—		TBD	Autoimmune disease	Phase I trial was initiated in January 2023

\* The above description of status in U.S. and Europe, “an application was 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.

### Nutraceuticals

In the nutraceutical business, the Group draws on its knowledge in the pharmaceutical business to conduct research and development of scientifically based original products in order to maintain and promote the health of people.

In the *SOYJOY* brand of soy snack bars, which delivers a convenient way to consume the nutrition of whole soybeans, *SOYJOY Fruits & Cheese* was launched in March 2023.

In the cosmetics\* field, focusing on healthy skin utilizing Otsuka's unique concepts and technology, as part of our male skin care brand *UL•OS*, in March 2023 we launched *UL•OS Scalp Shampoo Volume-up* for men concerned about the volume, texture, and resilience of their hair.

In the *EQUELLE* brand that supports women's health and beauty, we launched the new *EQUELLE Gelée* in April 2023 through medical facilities, pharmacists, and selected e-commerce sites in Japan. In addition to soy-derived equol, each pouch of refreshing orange-flavored *EQUELLE Gelée* offers all-in-one health and beauty support with vital ingredients such as vitamin D, collagen, and calcium.

Research and development expenses in the nutraceutical business for the nine-month period ended September 30, 2023 were ¥6,620 million.

\*: Cosmetics: cosmetics + medicine = Otsuka's unique concept for skin health products

### Consumer products

In the consumer product business, the Group is engaged in the research and development of original and unique products in the field of food and beverage that are part of everyone's daily life. The Group is creating and proposing innovative products based on the themes of food and health, targeting businesses in retort foods, beverages, and plant-based foods, with the aim of solving various issues associated with the changing society, such as those involving health, the environment, population and the aging society.

Research and development expenses in the consumer product business for the nine-month period ended September 30, 2023 were ¥506 million.

### Others

In the other businesses, the Group is primarily engaged in the research and development of specialty chemical products and fine chemicals. The Group is focusing on organic and inorganic synthesis technologies and conducting research and development of new products centered on own technology as well as next-generation fields.

Research and development expenses in the other businesses for the nine-month period ended September 30, 2023 were ¥3,789 million.

## (2) Consolidated Financial Position

### 1) Assets, Liabilities and Equity

(Millions of yen)

	As of December 31, 2022	As of September 30, 2023	Change
Current assets	1,192,030	1,353,542	161,512
Non-current assets	1,910,608	2,064,428	153,820
Total assets	3,102,638	3,417,971	315,332
Current liabilities	539,193	631,539	92,346
Non-current liabilities	301,076	260,643	(40,432)
Total liabilities	840,269	892,183	51,914
Total equity	2,262,369	2,525,788	263,418

#### a. Assets

Total assets as of September 30, 2023 were ¥3,417,971 million, an increase of ¥315,332 million compared to ¥3,102,638 million as of December 31, 2022. Current assets increased by ¥161,512 million, and non-current assets increased by ¥153,820 million.

##### (Current Assets)

Current assets as of September 30, 2023 were ¥1,353,542 million, an increase of ¥161,512 million compared to ¥1,192,030 million as of December 31, 2022. This was mainly due to increases in cash and cash equivalents by ¥47,004 million, trade and other receivables by ¥76,443 million, inventories by ¥27,638 million and other current assets by ¥10,267 million.

##### (Non-current Assets)

Non-current assets as of September 30, 2023 were ¥2,064,428 million, an increase of ¥153,820 million compared to ¥1,910,608 million as of December 31, 2022. This was mainly due to increases in property, plant and equipment by ¥28,369 million, goodwill by ¥27,753 million, investments accounted for using the equity method by ¥37,888 million, other financial assets by ¥21,130 million and deferred tax assets by ¥38,386 million.

#### b. Liabilities

Total liabilities as of September 30, 2023 were ¥892,183 million, an increase of ¥51,914 million compared to ¥840,269 million as of December 31, 2022. Current liabilities increased by ¥92,346 million, and non-current liabilities decreased by ¥40,432 million.

##### (Current Liabilities)

Current liabilities as of September 30, 2023 were ¥631,539 million, an increase of ¥92,346 million compared to ¥539,193 million as of December 31, 2022. This was mainly due to increases in bonds and borrowings by ¥14,391 million, other financial liabilities by ¥19,027 million, income taxes payable by ¥13,644 million and other current liabilities by ¥55,419 million, partially offset by a decrease in trade and other payables by ¥12,722 million. The increase in bonds and borrowings is due to the reclassification of current-portion of bonds to the current liabilities.

##### (Non-current Liabilities)

Non-current liabilities as of September 30, 2023 were ¥260,643 million, a decrease of ¥40,432 million compared to ¥301,076 million as of December 31, 2022. This was mainly due to decreases in bonds and borrowings by ¥23,432 million and other financial liabilities by ¥14,353 million.

#### c. Equity

Total equity as of September 30, 2023 was ¥2,525,788 million, an increase of ¥263,418 million compared to ¥2,262,369 million as of December 31, 2022. This was mainly due to an increase in retained earnings by ¥107,719 million which consisted of profit attributable to owners of the Company of ¥161,713 million net of dividend payments of ¥54,265 million and an increase in other components of equity by ¥149,686 million as a result of exchange rate fluctuations.

### 2) Cash Flows

Cash and cash equivalents as of September 30, 2023 were ¥518,639 million, an increase of ¥47,004 million compared to the balance as of December 31, 2022. For the nine-month period ended September 30, 2023, net cash flows provided by operating activities were ¥185,997 million, while net cash flows used in investing activities were ¥74,754 million mainly as a result of investments in the pharmaceutical business and nutraceuticals business toward sustainable growth. Net cash flows used in financing activities were ¥82,378 million as a result of repayments of borrowings and lease liabilities and ¥55,650 million of dividends paid.

Thus, cash and cash equivalents were increased to ¥518,639 million as operating cash inflows exceeded the total investing and financing cash outflows.

The following provides details around cash flow movements for the nine-month period ended September 30, 2023:

#### Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥185,997 million, an increase of ¥14,925 million compared to the figure for the nine-month period ended September 30, 2022. Cash flows provided by operating activities for the nine-month period ended September 30, 2023 mainly consisted of ¥213,208 million of profit before tax, adjusted for ¥70,273 million of depreciation and amortization expenses, ¥57,172 million of impairment losses and reversal of impairment losses, ¥41,084 million increase in trade and other receivables, ¥37,803 million decrease in trade and other payables and ¥74,739 million of income taxes paid.

The increase of ¥14,925 million in inflows was mainly due to a ¥67,208 million increase of profit before tax, driven by the growth of royalties and milestones for four global products and out-licensed products in the pharmaceutical business, which exceeded the decrease in cash flow

due to a ¥65,554 million decrease in inflow from trade and other receivables and a ¥43,470 million increase of income taxes paid.

#### Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥74,754 million, an increase in outflows of ¥14,344 million compared to the figure for the nine-month period ended September 30, 2022. Cash flows used in investing activities for the nine-month period ended September 30, 2023 mainly consisted of ¥61,926 million of payments for acquisition of property, plant and equipment, ¥15,905 million of proceeds from sales and redemption of investments and ¥25,376 million of payments for acquisition of investments. The increase of ¥14,344 million in outflows was primarily due to a ¥17,025 million increase of payments for acquisition of property, plant and equipment and a ¥18,317 million decrease of proceeds from sales and redemption of investments and a ¥7,403 million increase of payments for acquisition of investments, partially offset by a ¥33,397 million decrease of payments for acquisition of intangible assets.

#### Cash Flows from Financing Activities

Net cash flows used in financing activities were ¥82,378 million, a decrease in outflows of ¥1,639 million compared to the figure for the nine-month period ended September 30, 2022. Cash flows used in financing activities for the nine-month period ended September 30, 2023 mainly consisted of ¥10,327 million of repayments of long-term borrowings, ¥15,255 million of repayments of lease liabilities and ¥55,650 million of dividends paid.

### (3) Forecast for Consolidated Financial Results

In response to the consolidated operating results for the nine-month period ended September 30, 2023, the Company revised its consolidated operating results forecast for the fiscal year ending December 31, 2023 that it released on July 31, 2023 as follows:

Revisions of the consolidated operating results forecast for the fiscal year ending December 31, 2023

(Millions of yen)

	Previous forecast (A)	Revised forecast (B)	Amount of change (B) – (A)	Change (%)	(Reference) FY2022
Revenue	1,905,000	1,985,000	80,000	4.2	1,737,998
Business profit before research and development expenses	560,000	605,000	45,000	8.0	450,147
Business profit	270,000	300,000	30,000	11.1	174,917
Operating profit	245,000	245,000	0	0.0	150,323
Profit before tax	250,000	250,000	0	0.0	172,954
Profit for the year	192,000	192,000	0	0.0	137,280
Profit attributable to owners of the Company	188,000	188,000	0	0.0	133,906
Basic earnings per share (Yen)	346.44	346.44			246.80

Research and development expenses	290,000	305,000	15,000	5.2	275,230
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(Note) Forecast exchange rates are as follows:

	Previous forecast	Revised forecast
USD	132 yen	138 yen
EUR	142 yen	151 yen

Revenue was strong in all operating segments. In particular, business performance has been strong and surpassed the plan, driven by the four global products (*ABILIFY MAINTENA*, *REXULTI*, *JYNARQUE* and *LONSURF*) and royalties, milestones, etc. for out-licensed products in the pharmaceutical business, and by Nature Made in the nutraceutical business, and revenue is expected to exceed the previously announced forecast. Revenue is expected to exceed the previous forecast, even excluding the impact of exchange rate fluctuations.

Furthermore, business profit before research and development expenses is expected to exceed the previously announced forecast as gross profit was higher than planned due to strong sales of the four global products and royalties, milestones, etc. for out-licensed products.

On the other hand, research and development expenses are expected to exceed the previously announced forecast due to steady progress in research and development and the impact of exchange rate fluctuations.

Based on the above, business profit is expected to exceed the previously announced forecast.

Operating profit is expected to match the previously announced forecast due to revenue being stronger than planned, despite the recording of impairment losses related to products pertaining to a collaboration with Sumitomo Pharma Co., Ltd.

Furthermore, profit before tax and profit attributable to owners of the Company are expected to match the previously announced forecast.

2. Condensed Interim Consolidated Financial Statements and Major Notes  
(1) Condensed Interim Consolidated Statements of Financial Position

(Millions of yen)

	As of December 31, 2022	As of September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	471,634	518,639
Trade and other receivables	423,426	499,870
Inventories	223,507	251,145
Income taxes receivable	2,954	2,965
Other financial assets	17,481	17,624
Other current assets	52,934	63,202
Subtotal	1,191,939	1,353,445
Assets held for sale	91	96
Total current assets	1,192,030	1,353,542
Non-current assets		
Property, plant and equipment	510,674	539,044
Goodwill	335,442	363,196
Intangible assets	579,786	579,053
Investments accounted for using the equity method	241,743	279,631
Other financial assets	177,421	198,551
Deferred tax assets	53,383	91,769
Other non-current assets	12,156	13,181
Total non-current assets	1,910,608	2,064,428
Total assets	3,102,638	3,417,971

(Millions of yen)

	As of December 31, 2022	As of September 30, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	198,356	185,633
Bonds and borrowings	26,440	40,832
Lease liabilities	17,717	18,312
Other financial liabilities	3,307	22,334
Income taxes payable	28,340	41,984
Provisions	763	788
Contract liabilities	13,376	15,343
Other current liabilities	250,891	306,310
Total current liabilities	539,193	631,539
Non-current liabilities		
Bonds and borrowings	93,775	70,343
Lease liabilities	56,229	55,413
Other financial liabilities	30,515	16,162
Net defined benefit liabilities	16,011	16,448
Provisions	1,507	2,300
Contract liabilities	50,736	46,584
Deferred tax liabilities	29,511	28,451
Other non-current liabilities	22,787	24,939
Total non-current liabilities	301,076	260,643
Total liabilities	840,269	892,183
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	506,579	506,776
Treasury shares	(44,858)	(44,669)
Retained earnings	1,553,069	1,660,788
Other components of equity	128,773	278,460
Total equity attributable to owners of the Company	2,225,255	2,483,046
Non-controlling interests	37,114	42,741
Total equity	2,262,369	2,525,788
Total liabilities and equity	3,102,638	3,417,971

**(2) Condensed Interim Consolidated Statements of Income**

(Millions of yen)

	FY2022 (Nine-month period ended September 30, 2022)	FY2023 (Nine-month period ended September 30, 2023)
Revenue	1,266,119	1,479,080
Cost of sales	(427,016)	(445,354)
Gross profit	839,103	1,033,726
Selling, general and administrative expenses	(523,338)	(576,730)
Share of profit of investments accounted for using the equity method	3,696	17,125
Research and development expenses	(193,765)	(215,637)
Impairment losses	(30,697)	(57,172)
Other income	20,812	4,187
Other expenses	(961)	(2,849)
Operating profit	114,848	202,650
Finance income	35,177	14,551
Finance expenses	(4,026)	(3,993)
Profit before tax	145,999	213,208
Income tax expenses	(32,048)	(47,894)
Profit for the period	113,950	165,313
Attributable to:		
Owners of the Company	111,036	161,713
Non-controlling interests	2,914	3,600
Profit for the period	113,950	165,313
Earnings per share:		
Basic earnings per share (Yen)	204.66	297.99
Diluted earnings per share (Yen)	204.64	297.99

**(3) Condensed Interim Consolidated Statements of Comprehensive Income**

	(Millions of yen)	
	FY2022 (Nine-month period ended September 30, 2022)	FY2023 (Nine-month period ended September 30, 2023)
Profit for the period	113,950	165,313
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	127	274
Financial assets measured at fair value through other comprehensive income	5,727	4,772
Share of other comprehensive income of investments accounted for using the equity method	96	(178)
Subtotal	5,951	4,868
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	201,989	119,763
Cash flow hedges	(2)	(30)
Share of other comprehensive income of investments accounted for using the equity method	22,473	26,873
Subtotal	224,459	146,605
Total other comprehensive income	230,411	151,474
Total comprehensive income for the period	344,362	316,787
Attributable to:		
Owners of the Company	339,725	311,671
Non-controlling interests	4,636	5,116
Total comprehensive income for the period	344,362	316,787



**(4) Condensed Interim Consolidated Statements of Changes in Equity**  
FY2022 (Nine-month period ended September 30, 2022)

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Financial assets measured at fair value through other comprehensive income
Balance as of January 1, 2022	81,690	506,724	(45,572)	1,482,197	—	28,632
Changes in Accounting Policies	—	—	—	(37)	—	—
Restated balance	81,690	506,724	(45,572)	1,482,160	—	28,632
Profit for the period	—	—	—	111,036	—	—
Other comprehensive income	—	—	—	—	255	5,813
Comprehensive income for the period	—	—	—	111,036	255	5,813
Purchase of treasury shares	—	—	(0)	—	—	—
Dividends	—	—	—	(54,251)	—	—
Share-based payment transactions	—	(254)	714	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	1,419	(255)	(1,163)
Total transactions with owners	—	(254)	713	(52,831)	(255)	(1,163)
Balance as of September 30, 2022	81,690	506,470	(44,858)	1,540,364	—	33,282

	Equity attributable to owners of the Company					
	Other components of equity			Total	Non-controlling interests	Total equity
	Exchange differences on translation of foreign operations	Cash flow hedges	Total			
Balance as of January 1, 2022	(42,673)	(6)	(14,046)	2,010,994	34,195	2,045,189
Changes in Accounting Policies	—	—	—	(37)	0	(37)
Restated balance	(42,673)	(6)	(14,046)	2,010,956	34,195	2,045,152
Profit for the period	—	—	—	111,036	2,914	113,950
Other comprehensive income	222,622	(2)	228,689	228,689	1,722	230,411
Comprehensive income for the period	222,622	(2)	228,689	339,725	4,636	344,362
Purchase of treasury shares	—	—	—	(0)	—	(0)
Dividends	—	—	—	(54,251)	(1,338)	(55,589)
Share-based payment transactions	—	—	—	459	—	459
Transfer from other components of equity to retained earnings	—	—	(1,419)	—	—	—
Total transactions with owners	—	—	(1,419)	(53,792)	(1,338)	(55,130)
Balance as of September 30, 2022	179,949	(8)	213,223	2,296,890	37,494	2,334,384

## Equity attributable to owners of the Company

	Equity attributable to owners of the Company				Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Financial assets measured at fair value through other comprehensive income
Balance as of January 1, 2023	81,690	506,579	(44,858)	1,553,069	—	41,249
Profit for the period	—	—	—	161,713	—	—
Other comprehensive income	—	—	—	—	288	4,580
Comprehensive income for the period	—	—	—	161,713	288	4,580
Purchase of treasury shares	—	—	(1)	—	—	—
Dividends	—	—	—	(54,265)	—	—
Share-based payment transactions	—	248	190	—	—	—
Changes in ownership interests in subsidiaries that do not result in loss of control	—	(52)	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	272	(288)	16
Total transactions with owners	—	196	188	(53,993)	(288)	16
Balance as of September 30, 2023	81,690	506,776	(44,669)	1,660,788	—	45,846

## Equity attributable to owners of the Company

	Other components of equity			Total	Non-controlling interests	Total equity
	Exchange differences on translation of foreign operations	Cash flow hedges	Total			
Balance as of January 1, 2023	87,503	20	128,773	2,225,255	37,114	2,262,369
Profit for the period	—	—	—	161,713	3,600	165,313
Other comprehensive income	145,120	(30)	149,958	149,958	1,515	151,474
Comprehensive income for the period	145,120	(30)	149,958	311,671	5,116	316,787
Purchase of treasury shares	—	—	—	(1)	—	(1)
Dividends	—	—	—	(54,265)	(1,429)	(55,695)
Share-based payment transactions	—	—	—	439	—	439
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	(52)	1,941	1,888
Transfer from other components of equity to retained earnings	—	—	(272)	—	—	—
Total transactions with owners	—	—	(272)	(53,880)	511	(53,369)
Balance as of September 30, 2023	232,623	(10)	278,460	2,483,046	42,741	2,525,788

**(5) Condensed Interim Consolidated Statements of Cash Flows**

(Millions of yen)

	FY2022 (Nine-month period ended September 30, 2022)	FY2023 (Nine-month period ended September 30, 2023)
Cash flows from operating activities		
Profit before tax	145,999	213,208
Depreciation and amortization expenses	69,237	70,273
Impairment losses and reversal of impairment losses	30,697	57,172
Share of profit of investments accounted for using the equity method	(3,696)	(17,125)
Finance income	(35,177)	(14,551)
Finance expenses	4,026	3,993
Increase in inventories	(5,840)	(15,575)
Decrease (increase) in trade and other receivables	24,469	(41,084)
Decrease in trade and other payables	(42,164)	(37,803)
Others	7,526	32,255
Subtotal	<u>195,078</u>	<u>250,763</u>
Interest and dividends received	9,370	12,437
Interest paid	(2,108)	(2,464)
Income taxes paid	(31,268)	(74,739)
Net cash flows provided by operating activities	<u>171,071</u>	<u>185,997</u>
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	3,362	238
Payments for acquisition of property, plant and equipment	(44,900)	(61,926)
Payments for acquisition of intangible assets	(40,596)	(7,198)
Proceeds from sales and redemption of investments	34,223	15,905
Payments for acquisition of investments	(17,972)	(25,376)
Proceeds from sales of subsidiaries	8,323	-
(Increase) decrease in time deposits	(3,376)	4,684
Others	526	(1,082)
Net cash flows used in investing activities	<u>(60,410)</u>	<u>(74,754)</u>
Cash flows from financing activities		
Purchase of treasury shares	(0)	(1)
Change in short-term borrowings, net	2,660	(1,170)
Proceeds from long-term borrowings	1,061	11
Repayments of long-term borrowings	(17,524)	(10,327)
Repayments of lease liabilities	(14,740)	(15,255)
Dividends paid	(55,474)	(55,650)
Proceeds from issuance of common stock to non-controlling shareholders	-	2,021
Payments for acquisition of subsidiary interests from non-controlling shareholders	-	(2,007)
Net cash flows used in financing activities	<u>(84,018)</u>	<u>(82,378)</u>
Increase in cash and cash equivalents	26,642	28,864
Cash and cash equivalents at the beginning of the period	410,684	471,634
Effect of exchange rate changes on cash and cash equivalents	39,963	18,140
Cash and cash equivalents at the end of the period	<u>477,290</u>	<u>518,639</u>

## (6) Notes to Condensed Interim Consolidated Financial Statements

### Note to Going Concern Assumptions

Not applicable.

### Changes in Accounting Policies

The Group applied IAS 12 “Income Taxes” (amended in May 2021) from the three-month period ended March 31, 2023.

IFRS		Description of new standard, interpretations and amendments
IAS 12	Income Taxes	Clarification of accounting treatment for deferred taxes related to assets and liabilities arising from a single transaction

The application of this standard clarifies the accounting treatments on initial recognition for transaction that give rise to equal taxable and deductible temporary differences at the time of the transaction, and results in the recognition of taxable and deductible temporary differences as deferred tax liabilities and assets, respectively, in the Condensed Interim Consolidated Statements of Financial Position.

As a result of the application of the standard, the previous fiscal year’s consolidated financial statements have been retrospectively restated. The effect of the application decreased deferred tax assets by ¥77 million, increased deferred tax liabilities by ¥101 million, and decreased total equity by ¥178 million which consisted of decreases of retained earnings by ¥150 million, other components of equity by ¥1 million, and non-controlling interests by ¥26 million in the Condensed Interim Consolidated Statements of Financial Position as of December 31, 2022. In addition, the effect decreased income tax expenses by ¥5 million and increased profit for the period by ¥5 million in the Condensed Interim Consolidated Statements of Income for the nine-month period ended September 30, 2022.

Due to the cumulative effect of application of this standard, the beginning balance of retained earnings for the nine-month period ended September 30, 2022 decreased by ¥37 million in the Condensed Interim Consolidated Statements of Changes in Equity.

### Operating Segments

#### 1) Overview of reportable segments

The Group’s reportable segments are the constituent units of the Group for which separate financial information is available and which are subject to periodic reviews by the Board of Directors in order to make decisions on allocation of business resources and to evaluate the business performance of the respective segments.

The Company, as a holding company, directs the Group’s strategic planning and decision-making, monitors group operations and provides various common services to its group companies. Business activities are conducted by the Group’s subsidiaries and associates.

Centering on the healthcare business, the Group operates activities inside and outside Japan relating to the following four reportable segments: “Pharmaceuticals,” “Nutraceuticals,” “Consumer products” and “Others” businesses.

The Group defines the reportable segments as follows:

“Pharmaceuticals” comprises manufacturing and sales of prescription drugs and intravenous solutions.

“Nutraceuticals” comprises manufacturing and sales of functional beverages, over-the-counter drugs and nutritional supplements.

“Consumer products” comprises manufacturing and sales of mineral water, soft beverages and food products.

“Others” encompasses logistics, warehousing, manufacturing and sales of chemicals, evaluation systems for LED displays and spectroanalysis devices.

#### 2) Revenues and performance by reportable segment

Segment profit is based on operating profit.

Intersegment revenue and transfers reflect reasonable prices for intersegment transfers based on market value.

Revenues and performance by the Group’s reportable segments are as follows:

FY2022 (Nine-month period ended September 30, 2022)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	819,334	325,612	26,987	94,184	1,266,119	—	1,266,119
Intersegment revenue or transfers	—	18	18	31,915	31,952	(31,952)	—
Total	819,334	325,631	27,006	126,099	1,298,072	(31,952)	1,266,119
Segment profit	84,472	49,760	5,596	9,855	149,684	(34,835)	114,848

\* Adjustments to segment profit of ¥(34,835) million include intersegment eliminations of ¥170 million, unallocated corporate expenses of ¥(36,111) million and other income of ¥1,105 million. Corporate expenses are incurred in administrative departments such as headquarters.

FY2023 (Nine-month period ended September 30, 2023)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	992,416	359,031	28,440	99,192	1,479,080	—	1,479,080
Intersegment revenue or transfers	—	95	12	32,743	32,851	(32,851)	—
Total	992,416	359,126	28,453	131,936	1,511,932	(32,851)	1,479,080
Segment profit	191,501	28,278	10,594	9,705	240,079	(37,429)	202,650

\* Adjustments to segment profit of ¥(37,429) million include intersegment eliminations of ¥(385) million, unallocated corporate expenses of ¥(38,178) million and other income of ¥1,134 million. Corporate expenses are incurred in administrative departments such as headquarters.

### **Impairment of Assets**

FY2022 (Nine-month period ended September 30, 2022)

The Group recorded impairment losses of ¥30,697 million for the nine-month period ended September 30, 2022, ¥30,255 million of which related to the pharmaceutical business.

In the pharmaceutical business, the Group received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for vadadustat for the treatment of anemia during or prior to the dialysis phase, indicating that the application is not ready for approval in its present form. As a result, impairment losses of ¥23,584 million were recorded, with carrying amounts of in-process research and development recognized as intangible assets and other related assets reduced to zero.

FY2023 (Nine-month period ended September 30, 2023)

The Group recorded impairment losses of ¥57,172 million for the nine-month period ended September 30, 2023, ¥30,201 million of which related to the pharmaceutical business and ¥23,459 million related to the nutraceuticals business.

In the pharmaceutical business, the Group received results of clinical studies which relate to intangible assets (in-process research and development) recorded based on a collaboration and license agreement executed with Sumitomo Pharma Co., Ltd. for joint development and commercialization, indicating that DIAMOND 1 and DIAMOND 2 clinical studies (Phase III) evaluating “ulotaront” in acutely psychotic adults with schizophrenia did not meet their primary endpoint. Due to a confirmed delay beyond the initially anticipated approval application timeline, the Group re-evaluated the intangible assets. As a result, impairment losses of ¥23,106 million were recorded, with carrying amount of the intangible assets reduced to its recoverable amount, which is the value in use.

In the nutraceuticals business, the profitability of Daiya Foods, Inc., which develops, manufactures and sells plant-based foods in North America, declined as a result of increased competition in the dairy alternative cheese market in North America. Accordingly, the Group reduced the book value of the assets related to Daiya Foods Inc. to the recoverable amounts and recorded impairment losses of ¥22,229 million (¥12,488 million for goodwill, ¥2,434 million for trademarks, distribution rights and others and ¥7,306 million for other intangible assets). The recoverable amounts are measured at fair value less costs of disposal. The fair value less costs of disposal is measured primarily by taking into account the analysis of the income approach, and is calculated by discounting the estimated amount of future cash flows for the next 10 years, based on the business plan reflecting past experience and external information and being approved by management, using a discount rate of 10.0%, which is calculated as weighted average cost of capital. Beyond the projected period of the business plan, subsequent growth rate is estimated to be 3.0%. The hierarchy for the fair value is Level 3.