

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

July 31, 2023

Company name	: Otsuka Holdings Co., Ltd.
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
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Scheduled date of dividend payment commencement	: September 4, 2023
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 Second Quarter of the Fiscal Year Ending December 31, 2023 (January 1, 2023 to June 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 Q2	947,537	16.4	155,047	98.5	130,690	94.6	105,058	46.9	102,594	47.0	232,387	(5.0)
FY2022 Q2	814,307	13.3	78,126	(25.1)	67,146	(39.6)	71,524	(23.7)	69,770	(23.7)	244,724	69.2

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY2023 Q2	189.06	189.06
FY2022 Q2	128.61	128.57

*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 six-month period ended June 30, 2022, have been retrospectively restated.

*3 There is no dilution in basic earnings per share for the six-month period ended June 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 June 30, 2023	3,308,775	2,468,514	2,427,091	73.4	4,472.36
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	1,905,000	9.6	270,000	54.4	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 six-month period ended June 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):

June 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:

June 30, 2023	15,149,560 shares
December 31, 2022	15,201,916 shares
- 3) Average number of shares outstanding during the reporting period:

Six-month period ended June 30, 2023	542,650,435 shares
Six-month period ended June 30, 2022	542,477,429 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 8 for details with regard to the assumptions and other matters concerning the financial forecast.

The Company plans to hold an earnings release briefing for institutional investors, analysts and the press on July 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 six-month period ended June 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 June 30, 2023.

Summary of consolidated financial results for the six-month period ended June 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

	Six-month period ended June 30, 2022	Six-month period ended June 30, 2023	Change	% Change
Revenue	814,307	947,537	133,230	16.4 %
Business profit before research and development expenses	203,334	297,150	93,815	46.1 %
Business profit	78,126	155,047	76,920	98.5 %
Operating profit	67,146	130,690	63,544	94.6 %
Profit before tax	92,788	138,833	46,044	49.6 %
Profit for the period	71,524	105,058	33,534	46.9 %
Profit attributable to owners of the Company	69,770	102,594	32,824	47.0 %

Research and development expenses	125,208	142,103	16,894	13.5 %
Impairment losses	24,356	28,929	4,573	18.8 %

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 six-month period ended June 30, 2023 totaled ¥947,537 million (up 16.4% 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 V₂-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 V₂-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 ¥297,150 million (up 46.1%). The main factors were the aforementioned increased gross profit with increased sales for the four global products and increased royalties and milestones for out-licensed products, while the SG&A expense ratio decreased by appropriately controlling selling, general and administrative expenses through efficient investment in existing businesses while accelerating investment in new businesses.

Research and development expenses totaled ¥142,103 million (up 13.5%) 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 a challenge to the possibility of new treatments, 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 ¥155,047 million (up 98.5%).

Furthermore, operating profit increased to ¥130,691 million (up 94.6%). This can be attributed to the greater than anticipated growth in revenue, despite the recording of impairment losses in relation to Daiya Foods Inc., etc.

Profit for the period of ¥105,058 million (up 46.9%), and profit attributable to owners of the Company of ¥102,594 million (up 47.0%).

Revenue and business profit by business segment during FY2023 Q2

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	637,853	226,208	17,425	87,194	(21,144)	947,537
Business profit	137,262	28,479	8,097	6,773	(25,564)	155,047

Reference (FY2022 Q2)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	529,294	205,770	16,669	82,668	(20,095)	814,307
Business profit	65,023	28,132	1,754	6,093	(22,878)	78,126

1) Pharmaceuticals

Revenue for the six-month period ended June 30, 2023 totaled ¥637,853 million (up 20.5%), with business profit of ¥137,262 million (up 111.1%).

Main products

● Four global products

The Group positions the long acting antipsychotic agent *ABILIFY MAINTENA*, the antipsychotic agent *REXULTI*^{*1}/*RXULTI*^{*2}, the V₂-receptor antagonist *Samsca*/*JINARC*^{*3}/*JYNARQUE*^{*4} and the anti-cancer agent *LONSURF* as its four global products. Sales of those products totaled ¥337,138 million (up 15.8%).

*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 ¥96,008 million (up 25.8%).

• 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 for existing indications 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. In Japan, sales increased, boosted by new prescriptions due to enhancement of detailing activities for schizophrenia. As a result, sales of *REXULTI*/*RXULTI* totaled ¥96,045 million (up 27.0%).

• V₂-receptor antagonist *Samsca*

In Japan, although the number of prescriptions for autosomal dominant polycystic kidney disease (“ADPKD”) increased steadily, sales significantly decreased due to the impact of the switch to 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 switch to generics. As a result, sales of *Samsca* totaled ¥24,929 million (down 48.3%).

• V₂-receptor antagonist *JINARC*/*JYNARQUE*

In the U.S., the number of prescriptions for ADPKD increased mainly due to continued efforts to raise awareness of the disease and provide information about clinical data, as well as the impact of exchange rate fluctuations. As a result, sales of *JINARC*/*JYNARQUE* totaled ¥84,465 million (up 31.8%).

• Anti-cancer agent *LONSURF*

In the U.S., sales increased significantly due to increased awareness following the publication of a research paper concerning treatment in combination with bevacizumab, the recommendation of the combination therapy in NCCN Guidelines^{*5}, as well as the impact of exchange rate fluctuations. Prescriptions also continued to be solid in Japan due to increased awareness of the combination therapy following the publication of a research paper, etc. In Europe, the number of countries that have granted approval increased, and sales increased significantly. As a result, sales of *LONSURF* totaled ¥35,689 million (up 32.6%).

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

2) Nutraceuticals

Revenue for the six-month period ended June 30, 2023 totaled ¥226,208 million (up 9.9%), with business profit of ¥28,479 million (up 1.2%).

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 ¥147,517 million (up 15.5%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥13,528 million (down 4.4%).

● 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, the sales are growing due to the promotion of consumption accompanying rising interest in measures for heat disorder in daily life as well as due to an increase in drinking occasions, such as sports events, and other factors. 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. By building a brand image of a drink that provides hydration and replenishment of electrolytes through many years of initiatives, sales volume steadily increased and sales increased. 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^{*6} backed by enhanced awareness of physical conditioning among consumers and their high trust in the brand and quality, and also boosted by the impact of the expanded e-commerce and exchange rate fluctuations.

The Nutrition & Santé SAS brand, which sells health food products mainly in Europe, is expanding its food services^{*7} 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.

*6: IRI Data; Market Advantage; Calendar YTD 6/18/2023, Food, Drug, Mass Excluding Amazon and Costco

*7: 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^{*8}, although sales declined, efforts were made to strengthen activities for increasing awareness of the product value and to raise recognition and increase consumption of the product.

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

3) Consumer products

Revenue for the six-month period ended June 30, 2023 totaled ¥17,425 million (up 4.5%), while business profit totaled ¥8,097 million (up 361.5%) 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 of *MATCH*, a carbonated vitamin drink, increased due to aggressive marketing targeting high school students utilizing social networking services and due to an increase in people's activities, although sales volume declined slightly due to sales falling back from the strong sales of new products in the previous fiscal year.

4) Others

Revenue for the six-month period ended June 30, 2023 totaled ¥87,194 million (up 5.5%), while business profit totaled ¥6,773 million (up 11.2%) in part due to an increase in share of profit of investments accounted for using the equity method.

Sales in the specialty chemical business decreased marginally due to weak demand from the automotive and housing industries. Sales in the fine chemical business increased mainly due to an increase in sales of antibiotic intermediates.

In the transportation and warehousing business, sales were flat compared to the same period of the previous fiscal year as the acquisition of new external customers and the growth in handling volume proceeded steadily by strengthening the total healthcare distribution platform through coordination of logistics data, while the unit freight rates for international transportation, which had been on an upward trend, declined.

* 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 six-month period ended June 30, 2023 totaled ¥142,103 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 six-month period ended June 30, 2023 were ¥134,834 million.

Research and development activities in the pharmaceutical business carried out for the six-month period ended June 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	
Oncology	ASTX660 + ASTX727	—	tolinapant + decitabine, cedazuridine	U.S.	T-cell lymphoma	Phase I trial was initiated in February 2023
	AP24534	<i>ICLUSIG</i>	ponatinib	China	Chronic myeloid leukemia, acute lymphoblastic leukemia	An application was filed in March 2023
	TAS-120	<i>LYTGOBI</i>	futibatinib	Japan	Unresectable biliary tract cancer harboring FGFR2 gene fusions that has progressed after chemotherapy	Granted approval in June 2023
	TAS3351	—	—	Japan, U.S. and Europe	Non-small cell lung cancer	Phase I/II trial was initiated in June 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
	OPB-171775	—	—	Japan	Solid tumors	Discontinued for strategic reason
Cardio-vascular and renal system	ETC-1002	—	bempepoic 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

Category	Development Code	Brand Name	Generic Name	Area	Treatment/ Indication	Status*
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.

Furthermore, 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 six-month period ended June 30, 2023 were ¥4,307 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 six-month period ended June 30, 2023 were ¥336 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 six-month period ended June 30, 2023 were ¥2,624 million.

(2) Consolidated Financial Position

1) Assets, Liabilities and Equity

(Millions of yen)

	As of December 31, 2022	As of June 30, 2023	Change
Current assets	1,192,030	1,274,460	82,430
Non-current assets	1,910,608	2,034,315	123,706
Total assets	3,102,638	3,308,775	206,137
Current liabilities	539,193	580,915	41,722
Non-current liabilities	301,076	259,346	(41,729)
Total liabilities	840,269	840,261	(7)
Total equity	2,262,369	2,468,514	206,144

a. Assets

Total assets as of June 30, 2023 were ¥3,308,775 million, an increase of ¥206,137 million compared to ¥3,102,638 million as of December 31, 2022. Current assets increased by ¥82,430 million, and non-current assets increased by ¥123,706 million.

(Current Assets)

Current assets as of June 30, 2023 were ¥1,274,460 million, an increase of ¥82,430 million compared to ¥1,192,030 million as of December 31, 2022. This was mainly due to increases in cash and cash equivalents by ¥27,024 million, trade and other receivables by ¥15,785 million, inventories by ¥27,412 million and other current assets by ¥8,555 million.

(Non-current Assets)

Non-current assets as of June 30, 2023 were ¥2,034,315 million, an increase of ¥123,706 million compared to ¥1,910,608 million as of December 31, 2022. This was mainly due to increases in property, plant and equipment by ¥23,907 million, goodwill by ¥17,805 million, investments accounted for using the equity method by ¥28,572 million, other financial assets by ¥26,937 million and deferred tax assets by ¥15,573 million.

b. Liabilities

Total liabilities as of June 30, 2023 were ¥840,261 million, a decrease of ¥7 million compared to ¥840,269 million as of December 31, 2022. Current liabilities increased by ¥41,722 million, and non-current liabilities decreased by ¥41,729 million.

(Current Liabilities)

Current liabilities as of June 30, 2023 were ¥580,915 million, an increase of ¥41,722 million compared to ¥539,193 million as of December 31, 2022. This was mainly due to increases in bonds and borrowings by ¥15,933 million, other financial liabilities by ¥17,890 million, income taxes payable by ¥7,792 million and other current liabilities by ¥24,561 million, partially offset by a decrease in trade and other payables by ¥24,139 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 June 30, 2023 were ¥259,346 million, a decrease of ¥41,729 million compared to ¥301,076 million as of December 31, 2022. This was mainly due to decreases in bonds and borrowings by ¥22,025 million and other financial liabilities by ¥17,842 million.

c. Equity

Total equity as of June 30, 2023 was ¥2,468,514 million, an increase of ¥206,144 million compared to ¥2,262,369 million as of December 31, 2022. This was mainly due to an increase in retained earnings by ¥75,348 million which consisted of profit attributable to owners of the Company of ¥102,594 million net of dividend payments of ¥27,131 million and an increase in other components of equity by ¥126,197 million as a result of exchange rate fluctuations.

2) Cash Flows

Cash and cash equivalents as of June 30, 2023 were ¥498,659 million, an increase of ¥27,024 million compared to the balance as of December 31, 2022. For the six-month period ended June 30, 2023, net cash flows provided by operating activities were ¥113,533 million, while net cash flows used in investing activities were ¥54,334 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 ¥46,752 million as a result of repayments of borrowings and lease liabilities and ¥28,450 million of dividends paid.

Thus, cash and cash equivalents were increased to ¥498,659 million as operating cash inflows exceeded the total investing and financing cash outflows.

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

Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥113,533 million, a decrease of ¥5,292 million compared to the figure for the six-month period ended June 30, 2022. Cash flows provided by operating activities for the six-month period ended June 30, 2023 mainly consisted of ¥138,833 million of profit before tax, adjusted for ¥46,090 million of depreciation and amortization expenses, ¥28,929 million of impairment losses and reversal of impairment losses, ¥17,965 million increase in inventories, ¥34,851 million decrease in trade and other payables and ¥46,981 million of income taxes paid. The decrease of ¥5,292 million in inflows was mainly due to a ¥22,196 million increase in outflow from trade and other payables and a ¥25,508 million increase of income taxes paid, partially offset by a ¥46,044 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.

Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥54,334 million, a decrease in outflows of ¥1,697 million compared to the figure for the six-month period ended June 30, 2022. Cash flows used in investing activities for the six-month period ended June 30, 2023 mainly consisted of ¥43,004 million of payments for acquisition of property, plant and equipment, ¥12,143 million of proceeds from sales and redemption of investments and ¥21,750 million of payments for acquisition of investments. The decrease of ¥1,697 million in outflows was primarily due to a ¥35,794 million decrease of payments for acquisition of intangible assets, partially offset by a ¥12,338 million increase of payments for acquisition of property, plant and equipment and a ¥17,379 million decrease of proceeds from sales and redemption of investments.

Cash Flows from Financing Activities

Net cash flows used in financing activities were ¥46,752 million, a decrease in outflows of ¥1,464 million compared to the figure for the six-month period ended June 30, 2022. Cash flows used in financing activities for the six-month period ended June 30, 2023 mainly consisted of ¥8,285 million of repayments of long-term borrowings, ¥10,111 million of repayments of lease liabilities and ¥28,450 million of dividends paid.

(3) Forecast for Consolidated Financial Results

In response to the consolidated operating results for the six-month period ended June 30, 2023, the Company revised its consolidated operating results forecast for the fiscal year ending December 31, 2023 that it released on May 12, 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	1,800,000	1,905,000	105,000	5.8	1,737,998
Business profit before research and development expenses	485,000	560,000	75,000	15.5	450,147
Business profit	210,000	270,000	60,000	28.6	174,917
Operating profit	210,000	245,000	35,000	16.7	150,323
Profit before tax	210,000	250,000	40,000	19.0	172,954
Profit for the year	161,500	192,000	30,500	18.9	137,280
Profit attributable to owners of the Company	157,500	188,000	30,500	19.4	133,906
Basic earnings per share (Yen)	290.25	346.44			

Research and development expenses	275,000	290,000	15,000	5.5	275,230
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(Note) Forecast exchange rates are as follows:

	Previous forecast	Revised forecast
USD	130 yen	132 yen
EUR	138 yen	142 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, while the SG&A expense ratio decreased more than planned through efficient investment in existing businesses amid accelerated investment in new businesses.

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 exceed the previously announced forecast due to revenue being stronger than planned, despite the recording of impairment losses related to Daiya Foods Inc., etc.

Furthermore, profit before tax and profit attributable to owners of the Company are expected to exceed 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 June 30, 2023
Assets		
Current assets		
Cash and cash equivalents	471,634	498,659
Trade and other receivables	423,426	439,211
Inventories	223,507	250,919
Income taxes receivable	2,954	2,981
Other financial assets	17,481	21,101
Other current assets	52,934	61,490
Subtotal	1,191,939	1,274,364
Assets held for sale	91	96
Total current assets	1,192,030	1,274,460
Non-current assets		
Property, plant and equipment	510,674	534,582
Goodwill	335,442	353,248
Intangible assets	579,786	588,069
Investments accounted for using the equity method	241,743	270,315
Other financial assets	177,421	204,358
Deferred tax assets	53,383	68,956
Other non-current assets	12,156	14,783
Total non-current assets	1,910,608	2,034,315
Total assets	3,102,638	3,308,775

(Millions of yen)

	As of December 31, 2022	As of June 30, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	198,356	174,217
Bonds and borrowings	26,440	42,373
Lease liabilities	17,717	18,197
Other financial liabilities	3,307	21,197
Income taxes payable	28,340	36,132
Provisions	763	781
Contract liabilities	13,376	12,563
Other current liabilities	250,891	275,452
Total current liabilities	539,193	580,915
Non-current liabilities		
Bonds and borrowings	93,775	71,749
Lease liabilities	56,229	55,361
Other financial liabilities	30,515	12,673
Net defined benefit liabilities	16,011	16,356
Provisions	1,507	2,298
Contract liabilities	50,736	46,344
Deferred tax liabilities	29,511	27,696
Other non-current liabilities	22,787	26,865
Total non-current liabilities	301,076	259,346
Total liabilities	840,269	840,261
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	506,579	506,681
Treasury shares	(44,858)	(44,669)
Retained earnings	1,553,069	1,628,417
Other components of equity	128,773	254,971
Total equity attributable to owners of the Company	2,225,255	2,427,091
Non-controlling interests	37,114	41,423
Total equity	2,262,369	2,468,514
Total liabilities and equity	3,102,638	3,308,775

(2) Condensed Interim Consolidated Statements of Income

(Millions of yen)

	FY2022 (Six-month period ended June 30, 2022)	FY2023 (Six-month period ended June 30, 2023)
Revenue	814,307	947,537
Cost of sales	(274,287)	(287,862)
Gross profit	540,019	659,674
Selling, general and administrative expenses	(339,405)	(372,283)
Share of profit of investments accounted for using the equity method	2,720	9,759
Research and development expenses	(125,208)	(142,103)
Impairment losses	(24,356)	(28,929)
Other income	13,890	5,580
Other expenses	(514)	(1,006)
Operating profit	67,146	130,690
Finance income	28,175	10,538
Finance expenses	(2,532)	(2,395)
Profit before tax	92,788	138,833
Income tax expenses	(21,264)	(33,774)
Profit for the period	71,524	105,058
Attributable to:		
Owners of the Company	69,770	102,594
Non-controlling interests	1,753	2,464
Profit for the period	71,524	105,058
Earnings per share:		
Basic earnings per share (Yen)	128.61	189.06
Diluted earnings per share (Yen)	128.57	189.06

(3) Condensed Interim Consolidated Statements of Comprehensive Income

(Millions of yen)

	FY2022 (Six-month period ended June 30, 2022)	FY2023 (Six-month period ended June 30, 2023)
Profit for the period	71,524	105,058
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	94	203
Financial assets measured at fair value through other comprehensive income	(3,516)	10,393
Share of other comprehensive income of investments accounted for using the equity method	78	102
Subtotal	(3,343)	10,700
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	153,368	92,649
Cash flow hedges	0	18
Share of other comprehensive income of investments accounted for using the equity method	23,173	23,959
Subtotal	176,543	116,628
Total other comprehensive income	173,200	127,328
Total comprehensive income for the period	244,724	232,387
Attributable to:		
Owners of the Company	241,056	228,677
Non-controlling interests	3,668	3,710
Total comprehensive income for the period	244,724	232,387

(4) Condensed Interim Consolidated Statements of Changes in Equity
FY2022 (Six-month period ended June 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	—	—	—	69,770	—	—
Other comprehensive income	—	—	—	—	222	(3,473)
Comprehensive income for the period	—	—	—	69,770	222	(3,473)
Purchase of treasury shares	—	—	(0)	—	—	—
Dividends	—	—	—	(27,119)	—	—
Share-based payment transactions	—	(407)	714	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	802	(222)	(579)
Total transactions with owners	—	(407)	713	(26,317)	(222)	(579)
Balance as of June 30, 2022	81,690	506,316	(44,858)	1,525,613	—	24,579

	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	—	—	—	69,770	1,753	71,524
Other comprehensive income	174,536	0	171,285	171,285	1,914	173,200
Comprehensive income for the period	174,536	0	171,285	241,056	3,668	244,724
Purchase of treasury shares	—	—	—	(0)	—	(0)
Dividends	—	—	—	(27,119)	(1,338)	(28,457)
Share-based payment transactions	—	—	—	306	—	306
Transfer from other components of equity to retained earnings	—	—	(802)	—	—	—
Total transactions with owners	—	—	(802)	(26,813)	(1,338)	(28,151)
Balance as of June 30, 2022	131,862	(5)	156,436	2,225,199	36,525	2,261,725

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, 2023	81,690	506,579	(44,858)	1,553,069	—	41,249
Profit for the period	—	—	—	102,594	—	—
Other comprehensive income	—	—	—	—	217	10,543
Comprehensive income for the period	—	—	—	102,594	217	10,543
Purchase of treasury shares	—	—	(1)	—	—	—
Dividends	—	—	—	(27,131)	—	—
Share-based payment transactions	—	101	190	—	—	—
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	(114)	(217)	332
Total transactions with owners	—	101	188	(27,246)	(217)	332
Balance as of June 30, 2023	81,690	506,681	(44,669)	1,628,417	—	52,126

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	—	—	—	102,594	2,464	105,058
Other comprehensive income	115,301	18	126,082	126,082	1,245	127,328
Comprehensive income for the period	115,301	18	126,082	228,677	3,710	232,387
Purchase of treasury shares	—	—	—	(1)	—	(1)
Dividends	—	—	—	(27,131)	(1,423)	(28,554)
Share-based payment transactions	—	—	—	291	—	291
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	—	2,021	2,021
Transfer from other components of equity to retained earnings	—	—	114	—	—	—
Total transactions with owners	—	—	114	(26,841)	598	(26,242)
Balance as of June 30, 2023	202,804	39	254,971	2,427,091	41,423	2,468,514

(5) Condensed Interim Consolidated Statements of Cash Flows

(Millions of yen)

	FY2022 (Six-month period ended June 30, 2022)	FY2023 (Six-month period ended June 30, 2023)
Cash flows from operating activities		
Profit before tax	92,788	138,833
Depreciation and amortization expenses	45,240	46,090
Impairment losses and reversal of impairment losses	24,356	28,929
Share of profit of investments accounted for using the equity method	(2,720)	(9,759)
Finance income	(28,175)	(10,538)
Finance expenses	2,532	2,395
Increase in inventories	(4,669)	(17,965)
Decrease in trade and other receivables	22,563	12,993
Decrease in trade and other payables	(12,655)	(34,851)
Others	(1,152)	(1,038)
Subtotal	<u>138,109</u>	<u>155,089</u>
Interest and dividends received	3,509	7,001
Interest paid	(1,319)	(1,575)
Income taxes paid	(21,472)	(46,981)
Net cash flows provided by operating activities	<u>118,826</u>	<u>113,533</u>
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	2,586	216
Payments for acquisition of property, plant and equipment	(30,666)	(43,004)
Payments for acquisition of intangible assets	(38,894)	(3,100)
Proceeds from sales and redemption of investments	29,522	12,143
Payments for acquisition of investments	(13,183)	(21,750)
(Increase) decrease in time deposits	(5,835)	2,274
Others	437	(1,113)
Net cash flows used in investing activities	<u>(56,031)</u>	<u>(54,334)</u>
Cash flows from financing activities		
Purchase of treasury shares	(0)	(1)
Change in short-term borrowings, net	1,516	42
Proceeds from long-term borrowings	1,035	11
Repayments of long-term borrowings	(12,870)	(8,285)
Repayments of lease liabilities	(9,610)	(10,111)
Dividends paid	(28,288)	(28,450)
Proceeds from issuance of common stock to non-controlling shareholders	—	2,021
Payments for acquisition of subsidiary interests from non-controlling shareholders	—	(1,980)
Net cash flows used in financing activities	<u>(48,217)</u>	<u>(46,752)</u>
Increase in cash and cash equivalents	14,577	12,446
Cash and cash equivalents at the beginning of the period	410,684	471,634
Effect of exchange rate changes on cash and cash equivalents	31,497	14,578
Cash and cash equivalents at the end of the period	<u>456,759</u>	<u>498,659</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 ¥16 million and increased profit for the period by ¥16 million in the Condensed Interim Consolidated Statements of Income for the six-month period ended June 30, 2022.

Due to the cumulative effect of application of this standard, the beginning balance of retained earnings for the six-month period ended June 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 (Six-month period ended June 30, 2022)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	529,294	205,759	16,663	62,589	814,307	—	814,307
Intersegment revenue or transfers	—	11	5	20,078	20,095	(20,095)	—
Total	529,294	205,770	16,669	82,668	834,403	(20,095)	814,307
Segment profit	52,194	28,132	1,750	7,873	89,950	(22,804)	67,146

* Adjustments to segment profit of ¥(22,804) million include intersegment eliminations of ¥(24) million, unallocated corporate expenses of ¥(23,382) million and other income of ¥602 million. Corporate expenses are incurred in administrative departments such as headquarters.

FY2023 (Six-month period ended June 30, 2023)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	637,853	226,154	17,416	66,113	947,537	—	947,537
Intersegment revenue or transfers	—	54	9	21,080	21,144	(21,144)	—
Total	637,853	226,208	17,425	87,194	968,681	(21,144)	947,537
Segment profit	133,643	6,692	7,969	7,698	156,003	(25,312)	130,690

* Adjustments to segment profit of ¥(25,312) million include intersegment eliminations of ¥(226) million, unallocated corporate expenses of ¥(25,865) million and other income of ¥779 million. Corporate expenses are incurred in administrative departments such as headquarters.

Impairment of Assets

FY2022 (Six-month period ended June 30, 2022)

The Group recorded impairment losses of ¥24,356 million for the six-month period ended June 30, 2022, ¥24,150 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 (Six-month period ended June 30, 2023)

The Group recorded impairment losses of ¥28,929 million for the six-month period ended June 30, 2023, ¥21,940 million of which related to the nutraceuticals business and ¥6,921 million related to the pharmaceutical business.

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 ¥21,706 million (¥12,194 million for goodwill, ¥2,377 million for trademarks, distribution rights and others and ¥7,134 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.

In the pharmaceutical business, the ¥6,921 million in impairment losses represents the reduction of the book value to the recoverable amount, which is the value in use, of certain in-process research and development and of the trademarks, distribution rights and others for certain prescription drugs, because the initially anticipated profitability of these products is no longer expected.