

Consolidated Financial Results for the Fiscal Year Ended December 31, 2023 [IFRS]

February 14, 2024

Company name	: Otsuka Holdings Co., Ltd.
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
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Scheduled date of annual general meeting of shareholders	: March 28, 2024
Scheduled date of dividend payment commencement	: March 29, 2024
Scheduled date of securities report submission	: March 29, 2024
Supplementary materials for financial results	: Yes
Earnings announcement for 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 Fiscal Year Ended December 31, 2023

(1) Consolidated Operating Results

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

	Revenue		Business profit		Operating profit		Profit for the year		Profit attributable to owners of the Company		Total comprehensive income for the year	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
FY2023	2,018,568	16.1	312,553	78.7	139,612	(7.1)	125,499	(8.6)	121,616	(9.2)	227,764	(16.3)
FY2022	1,737,998	16.0	174,917	11.3	150,323	(2.7)	137,280	6.2	133,906	6.7	272,219	25.3

(Reference) Share of profit of investments accounted for using the equity method
 FY2023 ¥ 20,365 million
 FY2022 ¥ 5,780 million

- *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 fiscal year ended December 31, 2022, have been retrospectively restated.
- *3 There is no dilution in basic earnings per share for the fiscal year ended December 31, 2023.

	Basic earnings per share	Diluted earnings per share	Return on equity attributable to owners of the Company	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	Yen	Yen	%	%	%
FY2023	224.10	224.10	5.3	4.4	6.9
FY2022	246.80	246.78	6.3	5.8	8.6

(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 December 31, 2023	3,361,244	2,436,317	2,393,683	71.2	4,410.80
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.

(3) Consolidated Cash Flows

	Net cash flows provided by operating activities	Net cash flows used in investing activities	Net cash flows used in financing activities	Cash and cash equivalents at the end of the year
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
FY2023	283,232	(190,538)	(60,260)	513,341
FY2022	211,848	(81,575)	(95,474)	471,634

2. Dividends

	Annual dividends per share					Total dividends	Dividends pay-out ratio (consolidated)	Ratio of dividends to equity attributable to owners of the Company (consolidated)
	First quarter-end	Second quarter-end	Third quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
FY2022	–	50.00	–	50.00	100.00	54,263	40.5	2.6
FY2023	–	50.00	–	60.00	110.00	59,695	49.1	2.6
FY2024 (forecast)	–	60.00	–	60.00	120.00		26.0	

* Due to the application of IAS 12 “Income Taxes” (amended in May 2021), “Dividends pay-out ratio (consolidated)” and “Ratio of dividends to equity attributable to owners of the Company (consolidated)” for the fiscal year ended December 31, 2022, have been retrospectively restated.

3. Forecasts of Consolidated Operating Results for the Year Ending December 31, 2024 (January 1, 2024 to December 31, 2024)

(% indicates percentage of change from 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
Q2 (YTD)	1,037,000	9.4	164,500	6.1	168,000	28.5	128,000	21.8	126,000	22.8	232.17
FY2024	2,140,000	6.0	330,000	5.6	330,000	136.4	254,000	102.4	250,000	105.6	460.67

4. Others

(1) Changes in significant subsidiaries during the fiscal year (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. Consolidated Financial Statements and Major Notes (6) Notes to 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 fiscal year (including treasury shares):

December 31, 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 fiscal year:

December 31, 2023 15,149,580 shares

December 31, 2022 15,201,916 shares

3) Average number of shares outstanding during the fiscal year:

Fiscal year ended December 31, 2023 542,668,386 shares

Fiscal year ended December 31, 2022 542,556,212 shares

* This report is out of scope of audits 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. Overview of Operating Results and Financial Position (5) Forecasts of Consolidated Financial Results for the Fiscal Year Ending December 31, 2024” on page 10 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 February 14, 2024. Presentation materials and the webcast of the briefing will be available on the Company's website promptly after the briefing.

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1. Overview of Operating Results and Financial Position

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

(1) Operating Results for the Fiscal Year Ended December 31, 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)

	FY2022 (Fiscal year ended December 31, 2022)	FY2023 (Fiscal year ended December 31, 2023)	Change	% Change
Revenue	1,737,998	2,018,568	280,570	16.1 %
Business profit before research and development expenses	450,147	620,358	170,210	37.8 %
Business profit	174,917	312,553	137,636	78.7 %
Operating profit	150,323	139,612	(10,710)	(7.1)%
Profit before tax	172,954	142,655	(30,298)	(17.5)%
Profit for the year	137,280	125,499	(11,780)	(8.6)%
Profit attributable to owners of the Company	133,906	121,616	(12,290)	(9.2)%
Research and development expenses	275,230	307,804	32,574	11.8 %
Impairment losses	41,521	172,419	130,898	315.3 %

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. To anticipate social issues brought about by a highly uncertain world amid a changing social environment due to the impact of the geopolitical risks, etc., 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, and continue to pursue initiatives aimed at the realization of sustainable growth.

Revenue for the fiscal year ended December 31, 2023 totaled ¥2,018,568 million (up 16.1% over 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 ¥620,358 million (up 37.8%). 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 ¥307,804 million (up 11.8%) 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 ¥312,553 million (up 78.7%).

Operating profit decreased to ¥139,612 million (down 7.1%). The main factors were the impact of recording a total of ¥172,419 million in impairment losses in the fiscal year ended December 31, 2023 due to an impairment loss on AVP-786, a drug for agitation associated with dementia due to Alzheimer’s disease, in the fourth quarter of the fiscal year, in addition to impairment losses on products pertaining to Daiya Foods Inc. and to a collaboration with Sumitomo Pharma Co., Ltd. recorded through the third quarter of the fiscal year.

Profit for the year was ¥125,499 million (down 8.6%) and profit attributable to owners of the Company was ¥121,616 million (down 9.2%).

Results by business segment are as follows:

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	1,364,358	483,463	37,081	176,395	(42,730)	2,018,568
Business profit	278,057	59,652	17,823	7,717	(50,697)	312,553

Reference (FY2022)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	1,137,857	437,047	35,880	169,227	(42,014)	1,737,998
Business profit	151,875	54,195	7,135	9,047	(47,337)	174,917

1) Pharmaceuticals

Revenue in the pharmaceutical business for the fiscal year ended December 31, 2023 totaled ¥1,364,358 million (up 19.9%), with business profit of ¥278,057 million (up 83.1%).

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 ¥726,850 million (up 17.4%).

*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 ¥202,464 million (up 22.4%).

• 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. 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^{*5} advertising. 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 Japan, sales increased, boosted by new prescriptions due to enhancement of detailing activities for schizophrenia. As a result, sales of *REXULTI/RXULTI* totaled ¥212,509 million (up 25.6%).

*5: Direct to consumer

• V₂-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 ¥48,230 million (down 45.1%).

• V₂-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 ¥183,541 million (up 31.7%).

• 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*⁶ and the impact of exchange rate fluctuations. In Europe, sales increased 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, sales 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 ¥80,105 million (up 39.3%).

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

2) Nutraceuticals

Revenue in the nutraceutical business for the fiscal year ended December 31, 2023 totaled ¥483,463 million (up 10.6%), with business profit of ¥59,652 million (up 10.1%).

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 ¥312,998 million (up 14.8%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥27,851 million (down 2.3%).

● 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 increased during the summer this year, which had the highest temperatures on record*⁷, 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 hot spa facilities, and other factors including 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 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*⁸ in the U.S. backed by 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*⁹ and e-commerce. Although there was a 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 2023) throughout Japan were the highest since recordkeeping began in 1898.

*8: IRI Data: Market Advantage; Calendar YTD 12/31/2023, 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, grew 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 a steady increase in the number of e-commerce subscriptions.

As for *BODY MAINTÉ*, a protective beverage brand containing the plant-based lactic-acid bacteria B240*¹⁰, although sales declined, from December 2023, a new communication campaign has been started that proposes to manage one's physical condition on a daily basis in preparation for an important day, and efforts have been made to develop core users, 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 in the consumer product business for the fiscal year ended December 31, 2023 totaled ¥37,081 million (up 3.3%), while business profit totaled ¥17,823 million (up 149.8%) in part due to an increase in share of profit of associates.

In mineral water products, sales of mainstay brand *CRYSTAL GEYSER* remained on par with the previous fiscal year 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, and *MATCH Vitamin Mikan*, which was launched in October 2023.

4) Others

Revenue for the fiscal year ended December 31, 2023 totaled ¥176,395 million (up 4.2%), with business profit of ¥7,717 million (down 14.7%).

Sales in the specialty chemical business remained on par with the previous fiscal year, despite a delayed recovery in the semiconductor market and stagnation 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.

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

(2) **Research and Development Activities**

Research and development expenses for the fiscal year ended December 31, 2023 totaled ¥307,804 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 fiscal year ended December 31, 2023 were ¥292,028 million.

Research and development activities in the pharmaceutical business carried out for the fiscal year ended December 31, 2023 are summarized below.

Category	Development Code	Brand Name	Generic Name	Area	Treatment/ Indication	Status*
Psychiatry and neurology	OPC-34712	REXULTI / RXULTI	brexpiprazole	Japan	Major depressive disorder	Granted approval as an additional indication in December 2023
				Japan	Agitation associated with dementia due to Alzheimer's disease	An application was filed for approval of an additional indication in October 2023
				U.S.	Agitation associated with dementia due to Alzheimer's disease	Granted approval as an additional indication in May 2023
				Europe	Major depressive disorder	Discontinued for business reason
	Agitation associated with dementia due to Alzheimer's disease	Discontinued for business reason				
	aripiprazole long-acting injection	ABILIFY MAINTENA	aripiprazole	China	Schizophrenia	Granted approval in May 2023
	aripiprazole 2-month long-acting injection	ABILIFY ASIMTUFII		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	INAQOVI	decitabine, cedazuridine	Europe	Myelodysplastic syndromes	An application was filed for approval of an additional indication in December 2023
				China	Myelodysplastic syndromes	Phase I/II trial was initiated in October 2023
				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	ICLUSIG	ponatinib	China	Chronic myeloid leukemia, acute lymphoblastic leukemia	An application was filed in March 2023
TAS-116	Jeselhy	pimipespib	Japan	Prostate cancer	Phase II trial was initiated in September 2023	

Category	Development Code	Brand Name	Generic Name	Area	Treatment/ Indication	Status*
Oncology	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
				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, U.S. and Europe	Non-small cell lung cancer	Phase III trial was initiated in December 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	OPC-61815	<i>Samtasu</i>	tolvaptan sodium phosphate	China	Cardiac edema	An application was filed in December 2023
	—	—	voclosporin	Japan	Lupus nephritis	An application was filed in November 2023
	ETC-1002	—	bempeidoic acid	Japan	Hypercholesterolemia	Phase III trial was initiated in February 2023
	OPC-131461	—	—	Japan	Cardiac edema	Phase II trial was initiated in January 2023
Other categories	OPF-109	—	—	Japan	High-calorie parenteral nutrition for chronic renal failure	An application was filed.
	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 October 2023, the skin care brand “*InnerSignal*” released “*InnerSignal SC Rich Cream*,” a beauty cream developed with a focus on the stratification of the stratum corneum*.

Research and development expenses in the nutraceutical business for the fiscal year ended December 31, 2023 were ¥9,874 million.

* The outermost of four skin layers where cellular turnover takes place. For facial skin, this layer plays an important role in moisture retention and protective barrier functions.

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 fiscal year ended December 31, 2023 were ¥663 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 fiscal year ended December 31, 2023 were ¥5,238 million.

(3) Financial Position for the Fiscal Year Ended December 31, 2023

(Millions of yen)

	As of December 31, 2022	As of December 31, 2023	Change
Current assets	1,192,030	1,326,797	134,766
Non-current assets	1,910,608	2,034,446	123,838
Total assets	3,102,638	3,361,244	258,605
Current liabilities	539,193	667,233	128,040
Non-current liabilities	301,076	257,692	(43,383)
Total liabilities	840,269	924,926	84,657
Total equity	2,262,369	2,436,317	173,948

a. Assets

Total assets as of December 31, 2023 were ¥3,361,244 million, an increase of ¥258,605 million compared to ¥3,102,638 million as of December 31, 2022. Current assets increased by ¥134,766 million, and non-current assets increased by ¥123,838 million.

(Current Assets)

Current assets as of December 31, 2023 were ¥1,326,797 million, an increase of ¥134,766 million compared to ¥1,192,030 million as of December 31, 2022. This was mainly due to increases in cash and cash equivalents by ¥41,707 million, trade and other receivables by ¥50,660 million, inventories by ¥26,073 million and income taxes receivable by ¥16,656 million.

(Non-current Assets)

Non-current assets as of December 31, 2023 were ¥2,034,446 million, an increase of ¥123,838 million compared to ¥1,910,608 million as of December 31, 2022. This was mainly due to increases in property, plant and equipment by ¥42,683 million, goodwill by ¥43,606 million, investments accounted for using the equity method by ¥36,819 million, other financial assets by ¥20,465 million and deferred tax assets by ¥65,442 million, partially offset by a decrease in intangible assets by ¥88,815 million. Intangible assets decreased mainly due to the recording of totaling ¥130,898 million of impairment losses, including those related to AVP-786 under development for the treatment of agitation associated with dementia due to Alzheimer's disease, Daiya Foods Inc. and collaboration with Sumitomo Pharma Co., Ltd., while other various assets increased overall as a result of the depreciation of the yen. In addition to the impact of exchange rate fluctuations, there were also an increase in property, plant and equipment due to capital investment, increases in goodwill, trademarks, distribution rights and others due to the acquisition of Bonafide Health, LLC ("Bonafide Health"), and an increase in deferred tax assets due to increases of the elimination of unrealized gains on inventories and tax effect of impairment losses on intangible assets.

b. Liabilities

Total liabilities as of December 31, 2023 were ¥924,926 million, an increase of ¥84,657 million compared to ¥840,269 million as of December 31, 2022. Current liabilities increased by ¥128,040 million, and non-current liabilities decreased by ¥43,383 million.

(Current Liabilities)

Current liabilities as of December 31, 2023 were ¥667,233 million, an increase of ¥128,040 million compared to ¥539,193 million as of December 31, 2022. This was mainly due to increases in trade and other payables by ¥8,013 million, bonds and borrowings by ¥42,984 million, income taxes payable by ¥26,599 million and other current liabilities by ¥51,518 million. The increase in bonds and borrowings was due to the reclassification of current-portion of bonds to the current liabilities.

(Non-current Liabilities)

Non-current liabilities as of December 31, 2023 were ¥257,692 million, a decrease of ¥43,383 million compared to ¥301,076 million as of December 31, 2022. This was mainly due to decreases in bonds and borrowings by ¥24,575 million and other financial liabilities by ¥13,741 million.

c. Equity

Total equity as of December 31, 2023 was ¥2,436,317 million, an increase of ¥173,948 million compared to ¥2,262,369 million as of December 31, 2022. This was mainly due to an increase in retained earnings by ¥68,148 million which consisted of profit attributable to owners of the Company of ¥121,616 million net of dividend payments of ¥54,265 million and an increase in other components of equity by ¥100,440 million as a result of the depreciation of the yen.

(4) Cash Flow for the Fiscal Year Ended December 31, 2023

Cash and cash equivalents as of December 31, 2023 were ¥513,341 million, an increase of ¥41,707 million compared to the balance as of December 31, 2022. For the fiscal year ended December 31, 2023, net cash flows provided by operating activities were ¥283,232 million, while net cash flows used in investing activities were ¥190,538 million as a result of capital investments in the pharmaceutical business and nutraceuticals business toward sustainable growth as well as the acquisition of Bonafide Health in the nutraceuticals business. Net cash flows used in financing activities were ¥60,260 million as a result of repayments of borrowings and lease liabilities and ¥55,653 million of dividends paid.

Thus, cash and cash equivalents were increased to ¥513,341 million as operating cash inflows exceeded the total investing and financing cash outflows.

The following provides details around cash flow movements for the fiscal year ended December 31, 2023:

Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥283,232 million, an increase of ¥71,384 million compared to the previous fiscal year. Cash flows provided by operating activities for the fiscal year ended December 31, 2023 mainly consisted of ¥142,655 million of profit before tax, adjusted for ¥97,777 million of depreciation and amortization expenses, ¥172,419 million of impairment losses and reversal of impairment losses, ¥31,802 million increase in trade and other receivables and ¥80,982 million of income taxes paid.

Cash inflows from operating activities increased by ¥71,384 million from the previous fiscal year, despite the decrease in profit before tax due to the recording of impairment losses related to AVP-786, Daiya Foods Inc. and collaboration with Sumitomo Pharma Co., Ltd. and a ¥45,732 million increase in outflow of income taxes paid. This was due to the large growth of royalties and milestones for four global products and out-licensed products in the pharmaceutical business, which drove the business performance and contributed significantly to the increase in cash flow from operating activities.

Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥190,538 million, an increase in outflows of ¥108,963 million compared to the previous fiscal year. Cash flows used in investing activities for the fiscal year ended December 31, 2023 mainly consisted of ¥90,736 million of payments for acquisition of property, plant and equipment, ¥23,937 million of payments for acquisition of intangible assets, and ¥71,043 million of payments for acquisition of subsidiaries such as Bonafide Health, a company specializing in the creation and sale of products for women's health. The increase of ¥108,963 million in outflows was primarily due to a ¥29,787 million increase of payments for acquisition of property, plant and equipment and a ¥71,043 million increase of payments for acquisition of subsidiaries.

Cash Flows from Financing Activities

Net cash flows used in financing activities were ¥60,260 million, a decrease in outflows of ¥35,213 million compared to the previous fiscal year. Cash flows used in financing activities for the fiscal year ended December 31, 2023 mainly consisted of ¥27,954 million of a net increase in short-term borrowings, ¥11,935 million of repayments of long-term borrowings, ¥20,545 million of repayments of lease liabilities and ¥55,653 million of dividends paid.

(5) Forecasts of Consolidated Financial Results for the Fiscal Year Ending December 31, 2024

The financial forecast for the fiscal year ending December 31, 2024 is as follows:

(Millions of yen)

	FY2023 (actual)	FY2024 (forecast)	Change	% Change
Revenue	2,018,568	2,140,000	121,431	6.0%
Business profit before research and development expenses	620,358	638,000	17,641	2.8%
Business profit	312,553	330,000	17,446	5.6%
Operating profit	139,612	330,000	190,387	136.4%
Profit before tax	142,655	330,000	187,344	131.3%
Profit for the year	125,499	254,000	128,500	102.4%
Profit attributable to owners of the Company	121,616	250,000	128,383	105.6%
Research and development expenses	307,804	308,000	195	0.1%

(Note) FY2024 projected exchange rate: 138 Yen/USD 150 Yen/EUR

In the pharmaceutical business, revenue is expected to increase with results strongly driven by growth in royalty income from the four global products (*ABILIFY MAINTENA*, *REXULTI/RXULTI*, *JINARC/JYNARQUE* and *LONSURF*) and for out-licensed products. In the nutraceutical business, revenue is expected to increase due to growth in sales of three major brands (*POCARI SWEAT*, *Nature Made* and the Nutrition & Santé SAS brand) and three nurture brands (Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*).

Regarding selling, general and administrative expenses, the Group will engage in growth investment involving large new businesses that take on challenges in new frontiers. Meanwhile, the Group will also promote further cost adjustments in existing businesses.

Regarding research and development expenses, the Group expects to invest in sibeprenlimab/VIS649 under development for the treatment of IgA nephropathy, AVP-786 under development for the treatment of agitation associated with dementia due to Alzheimer's disease, and TAS6417 under development for the treatment of non-small cell lung cancer, among others, with a view toward achieving sustainable growth.

Business profit is expected to be higher than the one for the fiscal year ended December 31, 2023, as sales of the four global products and the nutraceutical business are expected to increase and further cost adjustments in existing businesses are promoted, despite promotion of investment in new businesses.

Operating profit is expected to increase due to recording substantial impairment losses during the year.

For the fiscal year ending December 31, 2024, the Company projects consolidated revenue of ¥2,140,000 million (up 6.0% over the current fiscal year), business profit before research and development expenses of ¥638,000 million (up 2.8%), business profit of ¥330,000 million (up 5.6%), operating profit of ¥330,000 million (up 136.4%), profit before tax of ¥330,000 million (up 131.3%), profit for the year of ¥254,000 million (up 102.4%), and profit attributable to owners of the Company of ¥250,000 million (up 105.6%).

2. Basic Rationale for Selection of Accounting Standards

The Group adopted International Financial Reporting Standards (IFRS) to enhance the international comparability of its financial reporting.

3. Consolidated Financial Statements and Major Notes

(1) Consolidated Statements of Financial Position

(Millions of yen)

	As of December 31, 2022	As of December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	471,634	513,341
Trade and other receivables	423,426	474,086
Inventories	223,507	249,581
Income taxes receivable	2,954	19,611
Other financial assets	17,481	16,062
Other current assets	52,934	54,113
Subtotal	1,191,939	1,326,797
Assets held for sale	91	—
Total current assets	1,192,030	1,326,797
Non-current assets		
Property, plant and equipment	510,674	553,358
Goodwill	335,442	379,048
Intangible assets	579,786	490,971
Investments accounted for using the equity method	241,743	278,562
Other financial assets	177,421	197,887
Deferred tax assets	53,383	118,825
Other non-current assets	12,156	15,792
Total non-current assets	1,910,608	2,034,446
Total assets	3,102,638	3,361,244

(Millions of yen)

	As of December 31, 2022	As of December 31, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	198,356	206,369
Bonds and borrowings	26,440	69,425
Lease liabilities	17,717	18,847
Other financial liabilities	3,307	—
Income taxes payable	28,340	54,939
Provisions	763	919
Contract liabilities	13,376	14,322
Other current liabilities	250,891	302,410
Total current liabilities	539,193	667,233
Non-current liabilities		
Bonds and borrowings	93,775	69,200
Lease liabilities	56,229	56,715
Other financial liabilities	30,515	16,774
Net defined benefit liabilities	16,011	16,557
Provisions	1,507	2,252
Contract liabilities	50,736	44,869
Deferred tax liabilities	29,511	27,170
Other non-current liabilities	22,787	24,152
Total non-current liabilities	301,076	257,692
Total liabilities	840,269	924,926
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	506,579	506,230
Treasury shares	(44,858)	(44,669)
Retained earnings	1,553,069	1,621,218
Other components of equity	128,773	229,214
Total equity attributable to owners of the Company	2,225,255	2,393,683
Non-controlling interests	37,114	42,634
Total equity	2,262,369	2,436,317
Total liabilities and equity	3,102,638	3,361,244

(2) Consolidated Statements of Income

(Millions of yen)

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Revenue	1,737,998	2,018,568
Cost of sales	(569,501)	(611,219)
Gross profit	1,168,496	1,407,348
Selling, general and administrative expenses	(724,129)	(807,355)
Share of profit of investments accounted for using the equity method	5,780	20,365
Research and development expenses	(275,230)	(307,804)
Impairment losses	(41,521)	(172,419)
Other income	23,445	5,729
Other expenses	(6,518)	(6,250)
Operating profit	150,323	139,612
Finance income	28,693	9,566
Finance expenses	(6,063)	(6,523)
Profit before tax	172,954	142,655
Income tax expenses	(35,673)	(17,155)
Profit for the year	137,280	125,499
Attributable to:		
Owners of the Company	133,906	121,616
Non-controlling interests	3,373	3,883
Profit for the period	137,280	125,499
Earnings per share:		
Basic earnings per share (Yen)	246.80	224.10
Diluted earnings per share (Yen)	246.78	224.10

(3) Consolidated Statements of Comprehensive Income

(Millions of yen)

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Profit for the year	137,280	125,499
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	(5,407)	1,344
Financial assets measured at fair value through other comprehensive income	8,937	5,373
Share of other comprehensive income of investments accounted for using the equity method	462	360
Subtotal	3,992	7,078
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	117,461	72,652
Cash flow hedges	26	22
Share of other comprehensive income of investments accounted for using the equity method	13,458	22,511
Subtotal	130,947	95,186
Total other comprehensive income	134,939	102,264
Total comprehensive income for the year	272,219	227,764
Attributable to:		
Owners of the Company	267,980	222,855
Non-controlling interests	4,238	4,909
Total comprehensive income for the year	272,219	227,764

(4) Consolidated Statements of Changes in Equity

FY2022 (From January 1, 2022 to December 31, 2022)

(Millions of yen)

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, 2022	81,690	506,724	(45,572)	1,482,197	—	28,632
Cumulative effects of changes in accounting policies	—	—	—	(37)	—	—
Restated balance	81,690	506,724	(45,572)	1,482,160	—	28,632
Profit for the year	—	—	—	133,906	—	—
Other comprehensive income	—	—	—	—	(5,091)	8,961
Comprehensive income for the year	—	—	—	133,906	(5,091)	8,961
Purchase of treasury shares	—	—	(0)	—	—	—
Dividends	—	—	—	(54,251)	—	—
Share-based payment transactions	—	(101)	714	—	—	—
Changes in ownership interests in subsidiaries that do not result in loss of control	—	(43)	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	(8,746)	5,091	3,655
Total transactions with owners	—	(144)	713	(62,997)	5,091	3,655
Balance as of December 31, 2022	81,690	506,579	(44,858)	1,553,069	—	41,249

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
Cumulative effects of 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 year	—	—	—	133,906	3,373	137,280
Other comprehensive income	130,176	26	134,074	134,074	864	134,939
Comprehensive income for the year	130,176	26	134,074	267,980	4,238	272,219
Purchase of treasury shares	—	—	—	(0)	—	(0)
Dividends	—	—	—	(54,251)	(1,342)	(55,593)
Share-based payment transactions	—	—	—	612	—	612
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	(43)	22	(21)
Transfer from other components of equity to retained earnings	—	—	8,746	—	—	—
Total transactions with owners	—	—	8,746	(53,682)	(1,320)	(55,002)
Balance as of December 31, 2022	87,503	20	128,773	2,225,255	37,114	2,262,369

FY2023 (From January 1, 2023 to December 31, 2023)

(Millions of yen)

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 year	—	—	—	121,616	—	—
Other comprehensive income	—	—	—	—	1,468	5,435
Comprehensive income for the year	—	—	—	121,616	1,468	5,435
Purchase of treasury shares	—	—	(1)	—	—	—
Dividends	—	—	—	(54,265)	—	—
Share-based payment transactions	—	(199)	190	—	—	—
Changes in ownership interests in subsidiaries that do not result in loss of control	—	(149)	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	798	(1,468)	669
Total transactions with owners	—	(349)	188	(53,467)	(1,468)	669
Balance as of December 31, 2023	81,690	506,230	(44,669)	1,621,218	—	47,355

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 year	—	—	—	121,616	3,883	125,499
Other comprehensive income	94,312	22	101,239	101,239	1,025	102,264
Comprehensive income for the year	94,312	22	101,239	222,855	4,909	227,764
Purchase of treasury shares	—	—	—	(1)	—	(1)
Dividends	—	—	—	(54,265)	(1,432)	(55,698)
Share-based payment transactions	—	—	—	(9)	—	(9)
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	(149)	2,043	1,893
Transfer from other components of equity to retained earnings	—	—	(798)	—	—	—
Total transactions with owners	—	—	(798)	(54,426)	610	(53,816)
Balance as of December 31, 2023	181,815	43	229,214	2,393,683	42,634	2,436,317

(5) Consolidated Statements of Cash Flows

(Millions of yen)

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Cash flows from operating activities		
Profit before tax	172,954	142,655
Depreciation and amortization expenses	93,761	97,777
Impairment losses and reversal of impairment losses	41,521	172,419
Share of profit of investments accounted for using the equity method	(5,780)	(20,365)
Finance income	(28,693)	(9,566)
Finance expenses	6,063	6,523
Increase in inventories	(21,700)	(16,560)
Increase in trade and other receivables	(22,481)	(31,802)
Increase (decrease) in trade and other payables	1,394	(13,012)
Others	773	23,257
Subtotal	<u>237,812</u>	<u>351,325</u>
Interest and dividends received	12,747	16,102
Interest paid	(3,460)	(3,212)
Income taxes paid	(35,250)	(80,982)
Net cash flows provided by operating activities	<u>211,848</u>	<u>283,232</u>
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	3,702	547
Payments for acquisition of property, plant and equipment	(60,949)	(90,736)
Payments for acquisition of intangible assets	(46,838)	(23,937)
Proceeds from sales and redemption of investments	43,526	20,962
Payments for acquisition of investments	(19,971)	(28,098)
Proceeds from sales of subsidiaries	8,323	-
Payments for acquisition of subsidiaries	-	(71,043)
(Increase) decrease in time deposits	(8,956)	2,741
Others	(411)	(974)
Net cash flows used in investing activities	<u>(81,575)</u>	<u>(190,538)</u>
Cash flows from financing activities		
Purchase of treasury shares	(0)	(1)
Change in short-term borrowings, net	4,436	27,954
Proceeds from long-term borrowings	1,073	12
Repayments of long-term borrowings	(25,671)	(11,935)
Repayments of lease liabilities	(19,729)	(20,545)
Dividends paid	(55,561)	(55,653)
Capital contribution from non-controlling interests	-	2,021
Payments for acquisition of interests in subsidiaries from non-controlling interests	-	(2,113)
Others	(21)	-
Net cash flows used in financing activities	<u>(95,474)</u>	<u>(60,260)</u>
Increase in cash and cash equivalents	34,798	32,432
Cash and cash equivalents at the beginning of the year	410,684	471,634
Effect of exchange rate changes on cash and cash equivalents	26,151	9,274
Cash and cash equivalents at the end of the year	<u>471,634</u>	<u>513,341</u>

(6) Notes to 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 fiscal year ended December 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 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 Consolidated Statements of Financial Position as of December 31, 2022. In addition, the effect increased income tax expenses by ¥139 million and decreased profit for the year by ¥139 million in the Consolidated Statements of Income for the fiscal year ended December 31, 2022.

Due to the cumulative effect of application of this standard, the beginning balance of retained earnings for the fiscal year ended December 31, 2022 decreased by ¥37 million in the Consolidated Statements of Changes in Equity.

Significant Accounting Estimates and Judgments

In preparing IFRS-compliant consolidated financial statements, management is required to make judgments, estimates and assumptions that may affect the application of accounting policies and the reported amounts of assets, liabilities, revenue and expenses. Actual results may differ from these estimates.

Such estimates and underlying assumptions are reviewed on an ongoing basis. The effects of the review of accounting estimates are recognized in the accounting period in which the review was conducted and future accounting periods. Items that may have significant effects on the amounts recognized in the consolidated financial statements are as follows:

- Impairment of intangible assets
- Fair value measurement of financial instruments
- Recoverability of deferred tax assets
- Measurement of defined benefit obligations
- Estimation of statutory and contractual rebates related to the public health system in the U.S.

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 (From January 1, 2022 to December 31, 2022)

(Millions of yen)

	Reportable segment					Adjustments* ¹	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	1,137,857	437,014	35,854	127,271	1,737,998	–	1,737,998
Intersegment revenue or transfers	–	32	26	41,955	42,014	(42,014)	–
Total	1,137,857	437,047	35,880	169,227	1,780,012	(42,014)	1,737,998
Segment profit	123,145	56,276	6,930	11,916	198,268	(47,945)	150,323
Other items							
Depreciation and amortization expenses	62,181	15,646	1,799	8,793	88,419	5,341	93,761
Share of profit (loss) of investments accounted for using the equity method	(6,860)	858	10,921	862	5,780	–	5,780
Impairment losses	38,287	2,040	237	108	40,674	847	41,521
Capital expenditures* ²	101,023	15,014	3,315	9,259	128,613	10,705	139,319

FY2023 (From January 1, 2023 to December 31, 2023)

(Millions of yen)

	Reportable segment					Adjustments* ¹	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	1,364,358	483,325	37,066	133,818	2,018,568	–	2,018,568
Intersegment revenue or transfers	–	138	14	42,577	42,730	(42,730)	–
Total	1,364,358	483,463	37,081	176,395	2,061,298	(42,730)	2,018,568
Segment profit	140,656	33,636	11,876	3,886	190,056	(50,443)	139,612
Other items							
Depreciation and amortization expenses	63,979	17,060	2,142	8,845	92,026	5,750	97,777
Share of profit (loss) of investments accounted for using the equity method	(808)	1,256	20,937	(1,027)	20,358	6	20,365
Impairment losses	136,677	26,065	4,604	5,051	172,398	21	172,419
Capital expenditures* ²	82,291	105,397	3,611	7,236	198,536	12,451	210,988

*1 Details of adjustments are as follows:

(1) Segment profit

The following table shows the segment profit adjustments.

(Millions of yen)

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Intersegment eliminations	(265)	(370)
Unallocated expenses*	(48,987)	(51,657)
Other income	1,307	1,584
Total	(47,945)	(50,443)

* Unallocated expenses are incurred in administrative departments such as headquarters of the Company and certain subsidiaries.

(2) Other items

Depreciation and amortization expenses and impairment losses

Adjustments include depreciation and amortization expenses and impairment losses of property, plant and equipment and intangible assets as assets associated with headquarters functions of the Company and certain subsidiaries.

(3) Capital expenditures

Adjustments include capital expenditures relating to assets associated with headquarters and research functions of the Company and certain subsidiaries.

*2 Capital expenditures are purchases of property, plant and equipment, goodwill and intangible assets.

Impairment of Assets

FY2022 (Fiscal year ended December 31, 2022)

The Group recorded impairment losses of ¥41,521 million for the fiscal year ended December 31, 2022, ¥38,286 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 (Fiscal year ended December 31, 2023)

The Group recorded impairment losses of ¥172,419 million for the fiscal year ended December 31, 2023, ¥136,677 million of which related to the pharmaceutical business and ¥26,065 million related to the nutraceutical business.

In the pharmaceutical business, the main impairment losses were ¥105,495 million in impairment loss of AVP-786 under development for the treatment of agitation associated with dementia due to Alzheimer's disease and ¥23,106 million in impairment loss related to intangible assets recorded based on a collaboration and license agreement executed with Sumitomo Pharma Co., Ltd. for joint development and commercialization.

Concerning AVP-786, the Group received results of Phase III of clinical studies (305 studies) targeting agitation associated with dementia due to Alzheimer's disease, indicating that the studies did not meet the primary endpoint. Due to a delay beyond the initially anticipated approval application timeline and diminished probability of market approval, the Group re-evaluated intangible assets (in-process research and development). As a result, impairment losses of ¥105,495 million were recorded, with carrying amount of the intangible assets reduced to its recoverable amount, which is the value in use. For calculation of the value in use, the discount rate (10.6%) based on the pre-tax weighted average cost of capital was used.

The Group received results of clinical studies which relate to intangible assets 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 (in-process research and development). 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. For calculation of the value in use, the discount rate (12.3%) based on the pre-tax weighted average cost of capital was used.

In the nutraceutical 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 carrying amount of the assets related to Daiya Foods Inc. to the recoverable amounts and recorded impairment losses of ¥24,828 million (¥12,707 million for goodwill, ¥2,477 million for trademarks, distribution rights and others and ¥9,643 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 12.8%, which is calculated as pre-tax 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.

Earnings per Share

(1) Basis of calculating basic earnings per share

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Profit attributable to owners of the Company (Millions of yen)	133,906	121,616
Amount not attributable to ordinary equity holders of the Company (Millions of yen)	–	–
Profit used for calculation of basic earnings per share (Millions of yen)	133,906	121,616
Weighted average number of ordinary shares (Thousands of shares)	542,556	542,668
Basic earnings per share (Yen)	246.80	224.10

(2) Basis of calculating diluted earnings per share

	FY2022 (From January 1, 2022 to December 31, 2022)	FY2023 (From January 1, 2023 to December 31, 2023)
Profit used for calculation of basic earnings per share (Millions of yen)	133,906	121,616
Adjustments of profit for the year (Millions of yen)	(10)	–
Profit used for calculation of diluted earnings per share (Millions of yen)	133,895	121,616
Weighted average number of ordinary shares (Thousands of shares)	542,556	542,668
Increase in ordinary shares	–	–
Weighted average number of diluted ordinary shares (Thousands of shares)	542,556	542,668
Diluted earnings per share (Yen)	246.78	224.10

* There is no dilution in earnings per share for FY2023.

Business Combinations

1. Significant business combinations

Acquisition of Bonafide Health, LLC

Pharmavite LLC (“Pharmavite”), a consolidated subsidiary of the Company, entered into an agreement to acquire all shares of Bonafide Health, LLC (“Bonafide Health”), a company specializing in the creation and sale of products for women’s health, and the acquisition was completed on November 30, 2023.

(1) Outline of business combination

(i) Name of acquired company and business description

Name of acquired company: Bonafide Health, LLC

Business description: Manufacture and sale of supplements and medical devices primarily aimed at women’s health

(ii) Main reasons for the business combination

Bonafide Health was founded in 2017 with a mission to contribute to women’s health by providing innovative, safe, and effective choices. The company is engaged in researching, developing and marketing new nature-inspired health products for women. Through the products of Bonafide Health, which are grounded in science and endorsed by healthcare professionals, the company addresses the complex health needs of women that evolve with age, offering long-term and sustained support.

Through the acquisition of Bonafide Health, Pharmavite will expand its existing portfolio in the women’s health field, comprised of Uqora, a novel urinary tract health brand; and *EQUELLE*, the supplement with equol.

(iii) Date of obtaining control

November 30, 2023

(iv) Method of obtaining control of the acquired company and percentage of equity with voting rights to be acquired

Pharmavite, a consolidated subsidiary of the Company, acquired 100% of shares with voting rights in Bonafide Health for cash consideration.

(2) Fair value of consideration paid, assets acquired and liabilities assumed as of the date control was obtained

(Millions of yen)

	Amount
Fair value of consideration paid	62,432
Cash	62,432
Fair value of assets acquired and liabilities assumed	
Current assets	2,943
Non-current assets	27,021
Current liabilities	(1,913)
Non-current liabilities	(134)
Fair value of assets acquired and liabilities assumed	27,916
Goodwill	34,515

- * ● The direct cost of the acquisition was ¥1,490 million and is included in “Selling, general and administrative expenses” in the consolidated statements of income.
- There are no acquired trade and other receivables, or contractual cash flows that are not expected to be collected.
 - Goodwill consists mainly of synergies with existing businesses and excess earning power that are expected to arise from the acquisition. There is no amount of goodwill that is expected to be deductible for tax purposes.
 - The major components of non-current assets allocated to intangible assets are ¥22,828 million in trademarks, distribution rights and others, and ¥4,015 million in other intangible assets.

(3) Impact on the Group’s financial results

Revenue and profit or loss included in the Group’s consolidated statement of income arising from Bonafide Health after the date of acquisition of control is immaterial. The disclosure of revenue and profit or loss assuming that the date of the business combination was January 1, 2023 (so-called “pro forma” information) has been omitted because the impact is immaterial.

2. Contingent consideration

Contingent considerations are recorded as a result of the business combinations involving Neurovance, Inc., ReCor Medical Inc., etc.

The contingent considerations from the acquisition of Neurovance, Inc. consist of the milestones to be paid based on the progress of the development of centanafadine, which is a compound under development as a treatment of ADHD, obtained when the Group acquired Neurovance, Inc. in March 2017, and the ones to be paid based on the revenue after the launch of centanafadine. The maximum potential amounts of the milestones will be USD 50 million and USD 750 million, respectively.

The contingent consideration, which is a milestone based on the development progress of the ultrasound renal denervation device acquired in the business combination with ReCor Medical Inc. in June 2018, was settled in December 2023.

The fair value of the contingent considerations is estimated based on the probability-weighted present value of the potential amount to be paid to the counterparty.

The fair value changes of the contingent considerations attributable to time value are recognized in “Finance expenses,” and the one attributable to changes of non-time-value is recognized in either “Other income” or “Other expenses.”

Changes in fair value of the contingent considerations are as follows:

(Millions of yen)

	Amount
Balance as of December 31, 2021	24,618
Changes in fair value	4,355
Foreign currency translation adjustment	2,396
Balance as of December 31, 2022	31,370
Changes in fair value	7,448
Settlement amount during the period	(23,668)
Foreign currency translation adjustment	1,059
Balance as of December 31, 2023	16,210

Subsequent Events

Not applicable.