

Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending December 31, 2022 [IFRS]

July 29, 2022

Company name	: Otsuka Holdings Co., Ltd.
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
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Scheduled date of quarterly securities report submission	: August 3, 2022
Scheduled date of dividend payment commencement	: September 5, 2022
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 Year Ending December 31, 2022 (January 1, 2022 to June 30, 2022)

(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	%
FY2022 Q2	814,307	13.3	78,126	(25.1)	67,146	(39.6)	71,508	(23.7)	69,753	(23.7)	244,712	69.2
FY2021 Q2	718,815	3.4	104,271	(8.5)	111,169	(5.8)	93,700	5.9	91,407	5.3	144,610	113.9

* 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

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY2022 Q2	128.58	128.54
FY2021 Q2	168.53	167.68

(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, 2022	3,101,281	2,261,750	2,225,225	71.8	4,100.78
As of December 31, 2021	2,820,915	2,045,189	2,010,994	71.3	3,707.64

2. Dividends

	Annual dividend per share				
	First Quarter end	Second Quarter end	Third Quarter end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
FY2021	–	50.00	–	50.00	100.00
FY2022	–	50.00	–	–	–
FY2022 (forecast)	–	–	–	50.00	100.00

* Revisions to dividends forecast most recently announced: None

3. Forecast of Consolidated Operating Results for the Year Ending December 31, 2022 (January 1, 2022 to December 31, 2022)
 (% 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
FY2022	1,670,000	11.5	160,000	1.8	152,000	(1.6)	138,000	6.8	135,000	7.6	248.82

* Revisions to financial forecast most recently announced: Yes

4. Others

- (1) Changes in significant subsidiaries during the six-month period ended June 30, 2022 (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: None
 - 2) Changes in accounting policies due to other reasons: None
 - 3) Changes in accounting estimates: None
- (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, 2022	557,835,617 shares
December 31, 2021	557,835,617 shares
 - 2) Number of shares of treasury shares as of the end of the reporting period:

June 30, 2022	15,201,896 shares
December 31, 2021	15,443,722 shares
 - 3) Average number of shares outstanding during the reporting period:

Six-month period ended June 30, 2022	542,477,429 shares
Six-month period ended June 30, 2021	542,357,387 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 Operating Results" on page 9 for details with regard to the assumptions and other matters concerning the financial forecast.

The Company plans to hold an earnings release conference call for institutional investors, analysts and the press on July 29, 2022. 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

(1) Consolidated Operating Results

The forward-looking statements in this report were prepared based on information available as of June 30, 2022.

Summary of consolidated operating results for the six-month period ended June 30, 2022

The Company and its subsidiaries (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)

	Six-month period ended June 30, 2021	Six-month period ended June 30, 2022	Change	% Change
Revenue	718,815	814,307	95,491	13.3 %
Business profit before research and development expenses	207,191	203,334	(3,856)	(1.9) %
Business profit	104,271	78,126	(26,145)	(25.1) %
Operating profit	111,169	67,146	(44,022)	(39.6) %
Profit before tax	119,207	92,788	(26,418)	(22.2) %
Profit for the period	93,700	71,508	(22,192)	(23.7) %
Profit attributable to owners of the Company	91,407	69,753	(21,653)	(23.7) %
Research and development expenses	102,919	125,208	22,288	21.7 %
Impairment losses	309	24,356	24,046	–

Based on the concept of total health care, the Group has been promoting corporate activities to maintain and promote health and to diagnose and treat disease. To respond to social issues brought about by a highly uncertain world amid a changing social environment due to the impact of the spread of COVID-19, 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, especially now, and continue to move toward the realization of sustainable growth.

For the six-month period ended June 30, 2022, the Group recorded consolidated revenue of ¥814,307 million (up 13.3% over the same period of the previous fiscal year) as revenue grew steadily mainly for the four global products (the long acting antipsychotic agent *ABILIFY MAINTENA*, the antipsychotic agent *REXULTI/RXULTI*, the V2-receptor antagonist *JYNARQUE* and the anti-cancer agent *LONSURF*). Even after excluding the impact from exchange rate fluctuations, this was a considerable growth in revenue. In the pharmaceutical business, business performance was driven by sales growth of the four global products and clinical nutrition. In the nutraceutical business, sales of *POCARI SWEAT* recovered, and sales of *Nature Made*, etc. grew in line with a rising awareness toward self-management of health. Moreover, consolidated revenue in the other businesses increased due to brisk sales of specialty chemical products and fine chemicals.

However, as a result of an increase in cost of sales due to the impact of exchange rate fluctuations on the elimination of unrealized gains on inventories in the pharmaceutical business, an increase in operating expenses due to resumption of operating activities, an increase in co-promotion expenses accompanying sales growth of *ABILIFY MAINTENA* and *REXULTI/RXULTI*, an increase in selling, general and administrative expenses due to the impact of exchange rate fluctuations, etc., and a decrease in share of profit of investments accounted for using the equity method, business profit before research and development expenses declined slightly to ¥203,334 million (down 1.9%).

Moreover, mainly due to an increase in development expenses based on a collaboration and license agreement executed with Sumitomo Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. for joint development and commercialization related to antipsychotic agent with a novel mechanism of action, an increase in development expenses for centanafadine under development for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients and binge-eating disorder, and an increase in development expenses for sibeprenlimab/VIS649 under development for the treatment of IgA nephropathy, as well as the impact of exchange rate fluctuations, research and development expenses totaled ¥125,208 million (up 21.7%). As a result, business profit was ¥78,126 million (down 25.1%).

The Group recorded impairment losses of ¥24,356 million related to vadadustat and others, and it also recorded a gain on valuation of its existing shareholding of Cullinan Pearl Corp. (hereinafter referred to as “Cullinan Pearl”) as a result of making Cullinan Pearl, which had been an equity-method affiliate of the Company, a wholly owned subsidiary. As a result, the Group recorded operating profit of ¥67,146 million (down 39.6%), profit for the period of ¥71,508 million (down 23.7%), and profit attributable to owners of the Company of ¥69,753 million (down 23.7%).

Revenue and business profit by business segment during 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

Reference (FY2021 Q2)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	472,467	175,311	15,211	73,893	(18,068)	718,815
Business profit	88,086	26,683	3,307	8,136	(21,941)	104,271

1) Pharmaceuticals

Although revenue for the six-month period ended June 30, 2022 totaled ¥529,294 million (up 12.0%), business profit was ¥65,023 million (down 26.2%) mainly due to the impact of exchange rate fluctuations on the elimination of unrealized gains on inventories and an increase in research and development expenses.

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 ¥291,165 million (up 23.4%).

*1: Brand name for the antipsychotic agent outside Japan and 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 disorder and schizophrenia patients, who have problems adhering to drug regimens, as well as an increase in face-to-face detailing activities. In Japan, sales were solid mainly due to the addition of an indication for the suppression of recurrence and relapse of mood episodes in bipolar I disorder in September 2020. Also in Europe, sales increased, particularly in major markets. As a result, sales of *ABILIFY MAINTENA* totaled ¥76,334 million (up 20.0%).

• Antipsychotic agent *REXULTI*/*RXULTI*

In the U.S., where antipsychotic agent *REXULTI* is sold as adjunctive therapy in major depressive disorder and a treatment for schizophrenia, prescriptions grew and sales increased, mainly due to the use of direct-to-consumer advertising, and an increase in face-to-face detailing activities. In Japan, sales were solid with the launch of orally disintegrating tablets in November 2021, increasing convenience, and stronger information provision activities. As a result, sales of *REXULTI*/*RXULTI* totaled ¥75,612 million (up 30.5%).

• V₂-receptor antagonist *Samsca*

In Japan, where the drug is sold as treatment for fluid retention in patients with heart failure and hepatic cirrhosis, ADPKD and another condition, sales increased due to online detailing activities such as web seminars. In the U.S., where the drug is sold as a treatment for hyponatremia, and in Europe, where the drug is sold as a treatment for hyponatremia caused by syndrome of inappropriate antidiuretic hormone secretion (SIADH), generics were launched after the expiry of the exclusive sales period. As a result, sales of *Samsca* totaled ¥48,210 million (up 10.4%).

• 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 a result, sales of *JINARC*/*JYNARQUE* totaled ¥64,088 million (up 33.4%).

• Anti-cancer agent *LONSURF*

In the U.S., sales increased since the use of oral anti-cancer agents is recommended due to the spread of COVID-19^{*5, 6}. Prescriptions continued to be robust in Japan and Europe. As a result, sales of *LONSURF* totaled ¥26,919 million (up 18.6%).

*5: Pelin Cinar et al., Safety at the Time of the COVID-19 Pandemic: How to Keep our Oncology Patients and Healthcare Workers Safe. J Natl Compr Canc Netw, 2020 Apr 15;1-6.

*6: ASCO. COVID-19 Patient Care Information, Cancer Treatment and Supportive Care. <https://www.asco.org/covid-resources/patient-care-info/cancer-treatment-supportive-care> Updated 17 September 2021, Accessed 19 July 2022.

2) Nutraceuticals

Revenue for the six-month period ended June 30, 2022 totaled ¥205,770 million (up 17.4%), with business profit of ¥28,132 million (up 5.4%).

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 ¥127,741 million (up 18.7%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥14,145 million (up 3.7%).

● Three major brands

Sales of *POCARI SWEAT*, an electrolyte supplement drink, increased in Japan amid the continuing impact of the spread of COVID-19 due to rising awareness among consumers regarding health management in addition to increased recognition of the importance of hydration and replenishment of electrolytes and promotion of consumption in daily life at home, etc. Overseas, sales of *POCARI SWEAT* increased overall for the brand, as a result of conducting education about hydration and replenishment of electrolytes and developing markets in line with the culture and situation in each region.

Amid a more sophisticated awareness of physical conditioning among consumers accompanying the spread of COVID-19, consumers' trust in the brand and quality of *Nature Made* supplements by Pharmavite LLC is further rising, and sales increased.

The Nutrition & Santé SAS brand, which sells health food products mainly in Europe, is expanding its food services^{*7} and e-commerce adapted to new lifestyles. Although local-currency sales decreased mainly due to the impact of stalled growth in the high value-added organic food market^{*8}, etc. accompanying a rapid rise in inflation in Europe and supply chain disruptions, Japanese yen-based sales increased due to exchange rate fluctuations.

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

*8: IRI Syndicated Retail Data, 2022 Apr-Jun

● Three nurture brands

Plant-based foods of the Daiya Foods Inc. brand saw a slight decrease in sales, mainly due to increased competition in dairy alternative cheese market in North America. However, efforts were continued 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 due to increased recognition of the product through the wide-ranging spread of information on the product.

As for *BODY MAINTÉ*, a protective beverage brand containing the plant-based lactic-acid bacteria B240^{*9}, although sales declined, efforts were made to strengthen activities for increasing awareness of the product value and to promote increased recognition and consumption of the product.

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

3) Consumer products

Although revenue for the six-month period ended June 30, 2022 totaled ¥16,669 million (up 9.6%), business profit was ¥1,754 million (down 47.0%) mainly due to the impact of rising transportation costs and exchange rate fluctuations, and a decrease in share of profit of investments accounted for using the equity method.

In mineral water products, sales of mainstay brand *CRYSTAL GEYSER* increased due to solid sales primarily of 700-milliliter PET bottles, although sales volume declined overall for the brand mainly due to a decrease in sales volume through the e-commerce and vending machine channels. Sales volume of *MATCH*, a carbonated vitamin drink, increased overall for the brand mainly due to an increase in outdoor temperatures, increased opportunities for activities by consumers, a growing awareness of health, and the launch of the new products *MATCH Muscat* and *MATCH Jelly Pineapple Blend*.

4) Others

Although revenue for the six-month period ended June 30, 2022 totaled ¥82,668 million (up 11.9%), business profit was ¥6,093 million (down 25.1%) mainly due to the impact of rising raw material costs and transportation costs, and a decrease in share of profit of investments accounted for using the equity method.

Sales in the specialty chemical business increased due to continuing favorable market conditions and adjustments in selling prices to more appropriate levels. Sales in the fine chemical business increased significantly, mainly due to an increase in sales of antibiotic intermediates.

In the transportation and warehousing business, sales increased due to the capture of new external customers in line with the promotion of a "common distribution platform" and an increase in the handling volume.

* Please refer to the Supplement Documents (FACT BOOK) for sales by product and other information.

<https://www.otsuka.com/en/ir/library/materials.html>

Impact of the situation involving Ukraine and Russia on business operations and operating results

The Group is deeply concerned about the current situation involving Ukraine and Russia (hereinafter referred to as "both countries"), and hopes for an early and peaceful resolution.

Regarding the impact on business operations and operating results for the six-month period ended June 30, 2022, the overall impact was limited despite some supply chain disruptions, impacts on clinical trials, etc.

Business sites

The Group does not have any business sites in both countries.

Sales

Although the anti-tuberculosis drug *Delytba* and others are sold through business partners in both countries, the impact on business operations and operating results is limited. Under its corporate philosophy, "Otsuka-people creating new products for better health worldwide," the Group will carefully monitor the situation and intends to do its utmost to ensure that the supply of *Delytba* and others is

maintained so that patients who need the drugs can receive them.

Supply chains

Despite some disruptions in supply chains, including international transportation, the impact on business operations and operating results is limited as a result of switching to alternative raw materials, changing transportation routes and other measures.

Research and Development

There are some impacts on clinical trials, and plans to launch clinical trial facilities and register patients in both countries have been put on hold. In order to minimize delays in ongoing clinical trials, the Group is responding by changing to other areas, etc. The Group also intends to do its utmost so that the supply of investigational drugs to the subjects participating in the clinical trials can be maintained and appropriate follow-up can be conducted.

Going forward, in the event that the impact of this situation becomes prolonged or more serious, the Group assumes that there will be further increases in raw material prices, supply chain disruptions, impacts of exchange rate fluctuations, etc., and will monitor the impact on business operations and operating results

Research and Development Activities

Research and development expenses for the six-month period ended June 30, 2022 totaled ¥125,208 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, 2022 were ¥118,580 million.

Research and development activities in the pharmaceutical business carried out for the six-month period ended June 30, 2022 are summarized below.

Category	Brand Name, (Generic name), Development Code	Status
Psychiatry and neurology	(centanafadine) EB-1020	<U.S.> • Phase II / III trial for the treatment of binge-eating disorder was initiated in February 2022.
	<i>REXULTI</i> (brexpiprazole) OPC-34712	<U.S.> • Development for the treatment of borderline personality disorder was halted due to development strategy.
	(aripiprazole 2-month long-acting injection)	<Europe> • An application for the indication of schizophrenia was filed in June 2022.
	(deuterium-modified dextromethorphan, quinidine) AVP-786	<U.S.> • Development for the treatment of intermittent explosive disorder was halted due to development strategy.
Oncology	(futibatinib) TAS-120	<U.S. and Europe> • An application for the indication of cholangiocarcinoma was filed in the U.S. in March 2022 and in Europe.
	(zimberelimab + pimitespib) AB122 + TAS-116	<Japan> • Phase I trial for the treatment of solid tumors* ¹ was initiated in February 2022.
	<i>Arokaris</i> (fosnetupitant) Pro-NETU	<Japan> • Approval was granted for the indication of chemotherapy-induced nausea and vomiting in March 2022.
	<i>Jeselhy</i> (pimitespib) TAS-116	<Japan> • Approval was granted for the indication of gastrointestinal stromal tumor in June 2022.
	TAS6417* ²	<U.S. and Europe> • Currently in Phase I / II trial for the treatment of non-small cell lung cancer.
Cardiovascular and renal system	<i>Samtasu</i> (tolvaptan sodium phosphate) OPC-61815	<Japan> • Approval was granted for the indication of cardiac edema in March 2022.
	(vadadustat) AKB-6548	<U.S. and Europe> • Otsuka Pharmaceutical has decided to terminate its global license agreements with Akebia Therapeutics, Inc. on May 13, 2022. These licenses were signed in December 2016 for the U.S. and April 2017 for Europe and other regions.
	(sibeprenlimab) VIS649	<U.S., Europe and Japan> • Phase III trial for the treatment of IgA nephropathy was initiated in April 2022.
Other categories	TAS5315	<Japan> • Phase II trial for the treatment of chronic spontaneous urticaria was initiated in June 2022.
	OPC-167832	<U.S.> • Phase II trial for tuberculosis was initiated in April 2022.

*1: pimitespib combination cohort during the Phase I trial in Japan for zimberelimab

*2: Entered into an agreement regarding the acquisition of Cullinan Pearl in May 2022.

Nutraceuticals

In the nutraceutical business, the Group draws on its knowledge in the pharmaceutical business to constantly conduct research and development of world-class products centering on functional foods and beverages that support the maintenance and improvement of day-to-day well-being. Otsu Nutraceuticals Research Institute of Otsuka Pharmaceutical Co., Ltd. conducted research based on the subject of “mucosal immunity,” which prevents the entry of pathogens into the body through mucous membranes, which are in contact with the outside environment. With respect to immunoglobulin A (hereinafter referred to as “IgA”^{*1}), which plays a central role in mucosal immunity, a research paper on an investigation on which microorganisms bound by IgA were present in saliva was accepted by *Bioscience of Microbiota, Food and Health*, which is a journal jointly established by three academic associations, The Intestinal Microbiology Society (IMS), Japan Society for Lactic Acid Bacteria, and Japanese Association for Food Immunology, and advance published on J-STAGE^{*2} on June 6, 2022. The results of this research indicated that salivary IgA may be able to inhibit infection by various pathogenic microorganisms while also indicating the importance of increasing IgA in saliva in order to prevent infection.

*1: IgA is a type of antibody. Although there are other antibodies, such as IgG, IgM and IgE, IgA plays an important role in mucous membranes by preventing the entry of pathogens.

*2: An electronic journal platform managed by the Japan Science and Technology Agency. J-STAGE publishes and provides access to electronic versions of *Bioscience of Microbiota, Food and Health* and many other journals.

Research and development expenses in the nutraceutical business for the six-month period ended June 30, 2022 were ¥3,817 million.

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, 2022 were ¥315 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 research and development of next-generation fields.

Research and development expenses in the other businesses for the six-month period ended June 30, 2022 were ¥2,494 million.

(2) Consolidated Financial Position

1) Assets, Liabilities and Equity

(Millions of yen)

	As of December 31, 2021	As of June 30, 2022	Change
Current assets	1,049,389	1,152,178	102,789
Non-current assets	1,771,526	1,949,102	177,576
Total assets	2,820,915	3,101,281	280,365
Current liabilities	467,910	529,371	61,461
Non-current liabilities	307,815	310,159	2,344
Total liabilities	775,725	839,530	63,805
Total equity	2,045,189	2,261,750	216,560

a. Assets

Total assets as of June 30, 2022 were ¥3,101,281 million, an increase of ¥280,365 million compared to ¥2,820,915 million as of December 31, 2021. Current assets increased by ¥102,789 million, and non-current assets increased by ¥177,576 million.

(Current Assets)

Current assets as of June 30, 2022 were ¥1,152,178 million, an increase of ¥102,789 million compared to ¥1,049,389 million as of December 31, 2021. This was mainly due to increases in cash and cash equivalents by ¥46,074 million, trade and other receivables by ¥9,465 million, inventories by ¥37,346 million and other current assets by ¥9,565 million.

(Non-current Assets)

Non-current assets as of June 30, 2022 were ¥1,949,102 million, an increase of ¥177,576 million compared to ¥1,771,526 million as of December 31, 2021. This was mainly due to exchange rate fluctuations, which primarily increased property, plant and equipment by ¥19,316 million, goodwill by ¥51,150 million, intangible assets by ¥90,943 million (including a ¥48,319 million increase in in-process research and development due to the fact that Cullinan Pearl became a wholly owned subsidiary) and investments accounted for using the equity method by ¥21,904 million.

b. Liabilities

Total liabilities as of June 30, 2022 were ¥839,530 million, an increase of ¥63,805 million compared to ¥775,725 million as of December 31, 2021. Current liabilities increased by ¥61,461 million, and non-current liabilities increased by ¥2,344 million.

(Current Liabilities)

Current liabilities as of June 30, 2022 were ¥529,371 million, an increase of ¥61,461 million compared to ¥467,910 million as of December 31, 2021. This was mainly due to increases in trade and other payables by ¥10,089 million, income taxes payable by ¥12,318 million and other current liabilities by ¥35,051 million.

(Non-current Liabilities)

Non-current liabilities as of June 30, 2022 were ¥310,159 million, an increase of ¥2,344 million compared to ¥307,815 million as of December 31, 2021. This was mainly due to increases in other financial liabilities by ¥2,867 million, net defined benefit liabilities by ¥1,358 million, deferred tax liabilities by ¥4,012 million and other non-current liabilities by ¥4,279 million, partially offset by decreases in bonds and borrowings by ¥6,006 million and contract liabilities by ¥4,967 million.

c. Equity

Total equity as of June 30, 2022 was ¥2,261,750 million, an increase of ¥216,560 million compared to ¥2,045,189 million as of December 31, 2021. This was mainly due to an increase in other components of equity by ¥170,487 million as a result of exchange rate fluctuations, and an increase in retained earnings by ¥43,436 million which consisted of profit attributable to owners of the Company of ¥69,753 million net of dividend payments of ¥27,119 million.

2) Cash Flows

Cash and cash equivalents as of June 30, 2022 were ¥456,759 million, an increase of ¥46,074 million compared to the balance as of December 31, 2021. For the six-month period ended June 30, 2022, net cash flows provided by operating activities were ¥118,826 million, while net cash flows used in investing activities were ¥56,031 million mainly as a result of investments in the pharmaceutical business toward sustainable growth. Net cash flows used in financing activities were ¥48,217 million as a result of repayments of borrowings and lease liabilities and ¥28,288 million of dividends paid.

Thus, cash and cash equivalents were increased to ¥456,759 million as operating cash inflows exceeded the total cash outflows from investing and financing activities, further augmented by the effect of ¥31,497 million of exchange rate fluctuations on cash and cash equivalents as a result of the depreciation of the yen.

The following provides details around cash flow movements for the six-month period ended June 30, 2022:

Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥118,826 million, a decrease of ¥9,112 million compared to the figure for the six-month period ended June 30, 2021. Cash flows from operating activities for the six-month period ended June 30, 2022 mainly consisted of ¥92,788 million of profit before tax, adjusted for ¥45,240 million of depreciation and amortization expenses, ¥24,356 million of impairment losses and reversal of impairment losses, ¥28,175 million of finance income, ¥22,563 million decrease in trade and other receivables, ¥12,655 million decrease in trade and other payables and ¥21,472 million of income taxes paid. The decrease of ¥9,112 million in inflows was primarily due to an ¥8,276 million decrease in inflow from trade and other receivables.

Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥56,031 million, an increase in outflows of ¥36,594 million compared to the figure for the six-month period ended June 30, 2021. Cash flows used in investing activities for the six-month period ended June 30, 2022 mainly consisted of ¥30,666 million of payments for acquisition of property, plant and equipment, ¥38,894 million of payments for acquisition of intangible assets including an asset acquisition of TAS6417 from Cullinan Pearl, ¥29,522 million of proceeds from sales and redemption of investments and ¥13,183 million of payments for acquisition of investments. The increase of ¥36,594 million in outflows was primarily due to a ¥30,387 million of payments for acquisition of intangible assets including an asset acquisition of TAS6417 in the pharmaceutical business, and a ¥22,170 million increase in outflow of time deposits, partially offset by a ¥17,039 million increase of proceeds from sales and redemption of investments.

Cash Flows from Financing Activities

Net cash flows used in financing activities were ¥48,217 million, a decrease in outflows of ¥503 million compared to the figure for the six-month period ended June 30, 2021. Cash flows from financing activities for the six-month period ended June 30, 2022 mainly consisted of ¥12,870 million of repayments of long-term borrowings, ¥9,610 million of repayments of lease liabilities and ¥28,288 million of dividends paid.

(3) Forecast for Consolidated Operating Results

In response to the consolidated operating results for the six-month period ended June 30, 2022, the Company revised its consolidated operating results forecast for the fiscal year ending December 31, 2022 that it released on May 13, 2022 as follows:

Revisions of the consolidated operating results forecast for the fiscal year ending December 31, 2022

(Millions of yen)

	Previous forecast (A)	Revised forecast (B)	Amount of change (B) – (A)	Change (%)	(Reference) FY2021
Revenue	1,550,000	1,670,000	120,000	7.7	1,498,276
Business profit before research and development expenses	437,000	430,000	(7,000)	(1.6)	389,427
Business profit	190,000	160,000	(30,000)	(15.8)	157,127
Operating profit	192,000	152,000	(40,000)	(20.8)	154,497
Profit before tax	191,000	177,000	(14,000)	(7.3)	163,638
Profit for the year	149,000	138,000	(11,000)	(7.4)	129,209
Profit attributable to owners of the Company	146,000	135,000	(11,000)	(7.5)	125,463
Basic earnings per share (Yen)	269.17	248.82			231.32

Research and development expenses	247,000	270,000	23,000	9.3	232,299
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(Note) Forecast exchange rates are as follows:

	Previous forecast	Revised forecast
USD	110 yen	125 yen
EUR	130 yen	136 yen

Revenue for the fiscal year ending December 31, 2022 is expected to exceed the previously announced forecast owing to stronger-than-forecasted performances in all businesses: the pharmaceutical business, which includes the four global products (*ABILIFY MAINTENA*, *REXULTI/RXULTI*, *JINARC/JYNARQUE* and *LONSURF*), as well as the nutraceutical business, consumer product business and other businesses. Revenue is expected to exceed the previous forecast, even excluding the impact of exchange rate fluctuations.

On the other hand, business profit before research and development expenses is expected to be lower than the previous forecast due to a significant impact from exchange rate fluctuations on cost of sales, including the impact from exchange rate fluctuations of approximately ¥20.0 billion relating to the elimination of unrealized gains on inventories in the pharmaceutical business, as well as an increase in co-promotion expenses accompanying sales growth of *ABILIFY MAINTENA* and *REXULTI/RXULTI*, a significant increase in selling, general and administrative expenses due to an impact from exchange rate fluctuations, and a decrease in share of profit of investments accounted for using the equity method. Furthermore, business profit was expected to be lower than the previous forecast as a result of a significant increase in research and development expenses due to the impact of exchange rate fluctuations. Excluding the impact of exchange rate fluctuations and one-time expenses, selling, general and administrative expenses excluding co-promotion expenses, business profit before research and development expenses, and research and development expenses are expected to be in line with the previous forecast.

Furthermore, operating profit, profit before tax, and profit attributable to owners of the Company are expected to be lower than the previous forecast due to the recording of impairment losses, etc. related to vadamastat and others.

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

(Millions of yen)

	As of December 31, 2021	As of June 30, 2022
Assets		
Current assets		
Cash and cash equivalents	410,684	456,759
Trade and other receivables	380,191	389,657
Inventories	180,350	217,696
Income taxes receivable	8,543	6,997
Other financial assets	20,074	19,437
Other current assets	48,036	57,601
Subtotal	1,047,880	1,148,150
Assets held for sale	1,508	4,027
Total current assets	1,049,389	1,152,178
Non-current assets		
Property, plant and equipment	487,089	506,406
Goodwill	295,735	346,886
Intangible assets	522,662	613,605
Investments accounted for using the equity method	227,790	249,694
Other financial assets	173,956	167,965
Deferred tax assets	31,936	45,623
Other non-current assets	32,355	18,920
Total non-current assets	1,771,526	1,949,102
Total assets	2,820,915	3,101,281

(Millions of yen)

	As of December 31, 2021	As of June 30, 2022
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	170,103	180,193
Bonds and borrowings	32,877	34,060
Lease liabilities	17,096	17,765
Other financial liabilities	1,988	3,295
Income taxes payable	10,490	22,809
Provisions	9,542	9,386
Contract liabilities	12,458	11,863
Other current liabilities	213,302	248,354
Subtotal	467,859	527,729
Liabilities directly associated with assets held for sale	50	1,642
Total current liabilities	467,910	529,371
Non-current liabilities		
Bonds and borrowings	102,754	96,748
Lease liabilities	59,726	60,461
Other financial liabilities	24,815	27,682
Net defined benefit liabilities	14,075	15,433
Provisions	1,358	1,422
Contract liabilities	57,771	52,804
Deferred tax liabilities	27,560	31,572
Other non-current liabilities	19,753	24,033
Total non-current liabilities	307,815	310,159
Total liabilities	775,725	839,530
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	506,724	506,316
Treasury shares	(45,572)	(44,858)
Retained earnings	1,482,197	1,525,634
Other components of equity	(14,046)	156,441
Total equity attributable to owners of the Company	2,010,994	2,225,225
Non-controlling interests	34,195	36,525
Total equity	2,045,189	2,261,750
Total liabilities and equity	2,820,915	3,101,281

(2) Condensed Interim Consolidated Statements of Income

(Millions of yen)

	FY2021 (Six-month period ended June 30, 2021)	FY2022 (Six-month period ended June 30, 2022)
Revenue	718,815	814,307
Cost of sales	(235,207)	(274,287)
Gross profit	483,607	540,019
Selling, general and administrative expenses	(283,052)	(339,405)
Share of profit of investments accounted for using the equity method	6,636	2,720
Research and development expenses	(102,919)	(125,208)
Impairment losses	(309)	(24,356)
Other income	8,702	13,890
Other expenses	(1,495)	(514)
Operating profit	111,169	67,146
Finance income	10,679	28,175
Finance expenses	(2,641)	(2,532)
Profit before tax	119,207	92,788
Income tax expenses	(25,506)	(21,280)
Profit for the period	93,700	71,508
Attributable to:		
Owners of the Company	91,407	69,753
Non-controlling interests	2,292	1,754
Profit for the period	93,700	71,508
Earnings per share:		
Basic earnings per share (Yen)	168.53	128.58
Diluted earnings per share (Yen)	167.68	128.54

(3) Condensed Interim Consolidated Statements of Comprehensive Income

(Millions of yen)

	FY2021 (Six-month period ended June 30, 2021)	FY2022 (Six-month period ended June 30, 2022)
Profit for the period	93,700	71,508
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	1,798	94
Financial assets measured at fair value through other comprehensive income	(15,202)	(3,516)
Share of other comprehensive income of investments accounted for using the equity method	(155)	78
Subtotal	(13,560)	(3,343)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	53,206	153,373
Cash flow hedges	0	0
Share of other comprehensive income of investments accounted for using the equity method	11,263	23,173
Subtotal	64,470	176,547
Total other comprehensive income	50,909	173,204
Total comprehensive income for the period	144,610	244,712
Attributable to:		
Owners of the Company	141,479	241,044
Non-controlling interests	3,130	3,668
Total comprehensive income for the period	144,610	244,712

(4) Condensed Interim Consolidated Statements of Changes in Equity
FY2021 (Six-month period ended June 30, 2021)

(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, 2021	81,690	506,295	(45,781)	1,402,644	—	43,298
Profit for the period	—	—	—	91,407	—	—
Other comprehensive income	—	—	—	—	1,843	(15,390)
Comprehensive income for the period	—	—	—	91,407	1,843	(15,390)
Purchase of treasury shares	—	—	(0)	—	—	—
Dividends	—	—	—	(27,116)	—	—
Share-based payment transactions	—	132	210	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	1,794	(1,843)	48
Total transactions with owners	—	132	209	(25,322)	(1,843)	48
Balance as of June 30, 2021	81,690	506,428	(45,571)	1,468,729	—	27,955

	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, 2021	(135,766)	(5)	(92,474)	1,852,375	31,057	1,883,432
Profit for the period	—	—	—	91,407	2,292	93,700
Other comprehensive income	63,619	0	50,071	50,071	838	50,909
Comprehensive income for the period	63,619	0	50,071	141,479	3,130	144,610
Purchase of treasury shares	—	—	—	(0)	—	(0)
Dividends	—	—	—	(27,116)	(1,721)	(28,838)
Share-based payment transactions	—	—	—	342	—	342
Transfer from other components of equity to retained earnings	—	—	(1,794)	—	—	—
Total transactions with owners	—	—	(1,794)	(26,774)	(1,721)	(28,496)
Balance as of June 30, 2021	(72,147)	(5)	(44,197)	1,967,080	32,466	1,999,546

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
Profit for the period	—	—	—	69,753	—	—
Other comprehensive income	—	—	—	—	222	(3,473)
Comprehensive income for the period	—	—	—	69,753	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)	1,525,634	—	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
Profit for the period	—	—	—	69,753	1,754	71,508
Other comprehensive income	174,540	0	171,290	171,290	1,914	173,204
Comprehensive income for the period	174,540	0	171,290	241,044	3,668	244,712
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	131,867	(5)	156,441	2,225,225	36,525	2,261,750

(5) Condensed Interim Consolidated Statements of Cash Flows

(Millions of yen)

	FY2021 (Six-month period ended June 30, 2021)	FY2022 (Six-month period ended June 30, 2022)
Cash flows from operating activities		
Profit before tax	119,207	92,788
Depreciation and amortization expenses	40,947	45,240
Impairment losses and reversal of impairment losses	309	24,356
Share of profit of investments accounted for using the equity method	(6,636)	(2,720)
Finance income	(10,679)	(28,175)
Finance expenses	2,641	2,532
Decrease (increase) in inventories	340	(4,669)
Decrease in trade and other receivables	30,840	22,563
Decrease in trade and other payables	(11,345)	(12,655)
Others	(2,862)	(1,152)
Subtotal	<u>162,763</u>	<u>138,109</u>
Interest and dividends received	3,338	3,509
Interest paid	(1,359)	(1,319)
Income taxes paid	(36,803)	(21,472)
Net cash flows provided by operating activities	<u>127,938</u>	<u>118,826</u>
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	1,403	2,586
Payments for acquisition of property, plant and equipment	(26,673)	(30,666)
Payments for acquisition of intangible assets	(8,507)	(38,894)
Proceeds from sales and redemption of investments	12,483	29,522
Payments for acquisition of investments	(14,650)	(13,183)
Decrease (increase) in time deposits	16,334	(5,835)
Others	171	437
Net cash flows used in investing activities	<u>(19,437)</u>	<u>(56,031)</u>
Cash flows from financing activities		
Purchase of treasury shares	(0)	(0)
Change in short-term borrowings, net	(250)	1,516
Proceeds from long-term borrowings	419	1,035
Repayments of long-term borrowings	(10,821)	(12,870)
Repayments of lease liabilities	(9,233)	(9,610)
Dividends paid	(28,835)	(28,288)
Net cash flows used in financing activities	<u>(48,721)</u>	<u>(48,217)</u>
Increase in cash and cash equivalents	59,779	14,577
Cash and cash equivalents at the beginning of the period	356,851	410,684
Effect of exchange rate changes on cash and cash equivalents	9,841	31,497
Cash and cash equivalents at the end of the period	<u>426,472</u>	<u>456,759</u>

(6) Notes to Condensed Interim Consolidated Financial Statements

Note to Going Concern Assumptions

Not applicable.

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 directs the Group's strategic planning, monitors group operations and provides various 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:

FY2021 (Six-month period ended June 30, 2021)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	472,467	175,290	15,202	55,855	718,815	—	718,815
Intersegment revenue or transfers	—	20	9	18,038	18,068	(18,068)	—
Total	472,467	175,311	15,211	73,893	736,884	(18,068)	718,815
Segment profit	93,478	26,824	3,315	9,395	133,014	(21,844)	111,169

* Adjustments to segment profit of ¥(21,844) million include intersegment eliminations of ¥42 million, unallocated corporate expenses of ¥(22,602) million and other income of ¥715 million. Corporate expenses are incurred in administrative departments such as headquarters.

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.

Impairment of Assets

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.

Acquisition of Full Ownership of Cullinan Pearl Corp. and Asset Acquisition of TAS6417

On June 21, 2022 (Japan time), Taiho Pharmaceutical Co., Ltd. (hereinafter referred to as “Taiho”), a consolidated subsidiary of the Company, acquired all shares of Cullinan Pearl (a then 20% equity-method affiliate of the Company) after the necessary legal proceedings, based on an agreement with Cullinan Oncology, Inc. (hereinafter referred to as “Cullinan Oncology”) on May 12, 2022 (Japan time), and Cullinan Pearl became a wholly owned subsidiary of the Company. Taiho made an upfront cash payment of \$275 million to Cullinan Oncology, with potential to pay up to an additional \$130 million based on the contractual milestone achievement. As a result of this acquisition, TAS6417, an epidermal growth factor receptor (EGFR) inhibitor discovered by Taiho, has been added to the Group’s pipeline.

The Group conducted a concentration test in accordance with the provisions of IFRS 3 “Business Combinations” for the above transaction and determined that substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, and that the integrated set of activities and assets acquired did not qualify as a business. Therefore, the Group accounted for this transaction as an asset acquisition. As for the Group’s equity interest in Cullinan Pearl held immediately before the date of acquisition, the Group remeasured it at its acquisition-date fair value and recognized a gain of ¥10,495 million in “Other income” in the condensed interim consolidated statements of income. The Group recorded ¥48,319 million of the consideration for the asset acquisition in “Intangible assets” (in-process research and development) on the condensed interim consolidated statements of financial position, which mainly consisted of the upfront payment and the fair value of the previously held equity interest.