

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

October 31, 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	: November 2, 2022
Scheduled date of dividend payment commencement	: -
Supplementary materials for quarterly financial results	: Yes
Earnings announcement for quarterly financial results	: Yes (for institutional investors, analysts and the press)

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

1. Consolidated Financial Results for the Third Quarter of the Year Ending December 31, 2022 (January 1, 2022 to September 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 Q3	1,266,119	14.3	125,694	(19.4)	114,848	(27.4)	113,945	(12.4)	111,030	(12.3)	344,361	81.6
FY2021 Q3	1,107,417	3.8	155,863	(17.4)	158,130	(7.9)	130,033	(0.4)	126,648	(0.9)	189,671	65.9

* 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 Q3	204.65	204.63
FY2021 Q3	233.50	233.34

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity attributable to owners of the Company per share
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of September 30, 2022	3,187,738	2,334,421	2,296,927	72.1	4,232.92
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	1,710,000	14.1	160,000	1.8	142,000	(8.1)	134,000	3.7	131,000	4.4	241.46

* Revisions to financial forecast most recently announced: Yes

4. Others

- (1) Changes in significant subsidiaries during the nine-month period ended September 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):

September 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:

September 30, 2022	15,201,916 shares
December 31, 2021	15,443,722 shares
 - 3) Average number of shares outstanding during the reporting period:

Nine-month period ended September 30, 2022	542,530,099 shares
Nine-month period ended September 30, 2021	542,372,023 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 10 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 October 31, 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 September 30, 2022.

Summary of consolidated operating results for the nine-month period ended September 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)

	Nine-month period ended September 30, 2021	Nine-month period ended September 30, 2022	Change	% Change
Revenue	1,107,417	1,266,119	158,701	14.3 %
Business profit before research and development expenses	318,384	319,460	1,075	0.3 %
Business profit	155,863	125,694	(30,168)	(19.4) %
Operating profit	158,130	114,848	(43,282)	(27.4) %
Profit before tax	166,308	145,999	(20,308)	(12.2) %
Profit for the period	130,033	113,945	(16,087)	(12.4) %
Profit attributable to owners of the Company	126,648	111,030	(15,617)	(12.3) %
Research and development expenses	162,521	193,765	31,244	19.2 %
Impairment losses	5,051	30,697	25,646	507.7 %

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 nine-month period ended September 30, 2022, the Group recorded consolidated revenue of ¥1,266,119 million (up 14.3% over the same period of the previous fiscal year), even after excluding the impact from exchange rate fluctuations. This was mainly due to business performance driven by sales growth of 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), clinical nutrition and INQOVI in the pharmaceutical business, as well as sales recovery of POCARI SWEAT and sales growth of Nature Made, etc. in line with a rising awareness toward self-management of health in the nutraceutical business. Moreover, sales of specialty chemical products and fine chemicals business in the other businesses were brisk.

Business profit before research and development expenses was ¥319,460 million (up 0.3%), about the same level as in the same period of the previous fiscal year. This was mainly due to an increase in cost of sales caused by 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 caused by the impact of exchange rate fluctuations, etc., and a decrease in share of profit of investments accounted for using the equity method.

Research and development expenses totaled ¥193,765 million (up 19.2%) mainly due to an increase in development expenses for centanafadine under development for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients, etc., steady progress for sibprenlimab/VIS649 which is under development for the treatment of IgA nephropathy, and in addition, 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 as a challenge to the possibility of new treatments. There was also the impact of exchange rate fluctuations.

As a result of these aggressive research and development investments, business profit was ¥125,694 million (down 19.4%).

The operating profit was ¥114,848 million (down 27.4%). The main factor was that the Group recorded to other income 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. However, the Group recorded impairment losses on certain property, plant and equipment and intangible assets (mainly trademarks, distribution rights and others) in the medical devices business in the three-month period ended September 30, 2022 as a result of the decision to concentrate on priority projects in that business, in addition to impairment losses on the intangible assets, etc. pertaining to vadadustat already recorded in the three-month period ended March 31, 2022. Total impairment losses recorded during the nine-month period ended September 30, 2022 amounted to ¥30,697 million.

Profit for the period of ¥113,945 million (down 12.4%), and profit attributable to owners of the Company of ¥111,030 million (down 12.3%).

Revenue and business profit by business segment during FY2022 Q3

(Millions of yen)

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

Reference (FY2021 Q3)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	720,974	280,072	24,115	110,752	(28,496)	1,107,417
Business profit	126,854	45,905	5,767	10,813	(33,478)	155,863

1) Pharmaceuticals

Although revenue for the nine-month period ended September 30, 2022 totaled ¥819,334 million (up 13.6%), business profit was ¥101,346 million (down 20.1%) 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 ¥454,498 million (up 26.0%).

*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 significantly 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, and the impact of exchange rate fluctuations. 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 ¥120,413 million (up 24.5%).

• 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 significantly increased, mainly due to the use of direct-to-consumer advertising, and an increase in face-to-face detailing activities, as well as the impact of exchange rate fluctuations. 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 ¥121,469 million (up 36.5%).

• 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 Japan, as treatment for fluid retention in patients with heart failure and hepatic cirrhosis, 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 ¥70,725 million (up 6.0%).

• V₂-receptor antagonist *JINARC/JYNARQUE*

In the U.S., the number of prescriptions for ADPKD increased mainly due to continued efforts to raise awareness of the disease and provide information about clinical data, as well as the impact of exchange rate fluctuations. As a result, sales of *JINARC/JYNARQUE* totaled ¥99,931 million (up 34.5%).

• Anti-cancer agent *LONSURF*

In the U.S., sales have significantly increased as the use of oral anti-cancer agents has been recommended since the spread of COVID-19^{*5, 6}, and there also was the impact of exchange rate fluctuations. Prescriptions continued to be solid in Japan and Europe. As a result, sales of *LONSURF* totaled ¥41,958 million (up 23.1%).

*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> Accessed 19 October 2022.

2) Nutraceuticals

Revenue for the nine-month period ended September 30, 2022 totaled ¥325,631 million (up 16.3%), with business profit of ¥46,299 million (up 0.9%), mainly due to the sharp rise in raw material costs and the recovery in sales activities.

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 ¥202,816 million (up 17.5%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥21,160 million (up 3.8%).

● Three major brands

Sales of *POCARI SWEAT*, an electrolyte supplement drink, increased in Japan due to factors that include rising awareness among consumers regarding health management, increased recognition of the importance of hydration and replenishment of electrolytes, promotion of consumption in daily life at home, and an increase in drinking occasions accompanying resumption of outdoor events. 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, sales of *Nature Made* supplements by Pharmavite LLC were solid, backed by consumers' trust in the brand and quality.

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 slightly 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 France Grocery Retailers - Organic food category Retail Sales, 2022 Jan-Sep

● Three nurture brands

Plant-based foods of the Daiya Foods Inc. brand saw a decrease in local-currency sales, mainly due to increased competition in the dairy alternative cheese market in North America. However, Japanese yen-based sales remained level year on year due to the impact of exchange rate fluctuations. 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

Revenue for the nine-month period ended September 30, 2022 totaled ¥27,006 million (up 12.0%). Business profit was ¥5,842 million (up 1.3%) mainly due to the impact of rising transportation costs and exchange rate fluctuations.

In mineral water products, sales of mainstay brand *CRYSTAL GEYSER* increased due to strong sales 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. Amid a growing awareness of health among people, sales volume of *MATCH*, a carbonated vitamin drink, increased overall for the brand mainly due to the launch of the new products *MATCH Muscat* and *MATCH Jelly Pineapple Blend* in addition to the existing products.

4) Others

Although revenue for the nine-month period ended September 30, 2022 totaled ¥126,099 million (up 13.9%), business profit was ¥7,398 million (down 31.6%) 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 adjustments in selling prices to more appropriate levels and favorable market conditions in the first half of the fiscal year. Sales in the fine chemical business increased significantly, mainly due to an increase in sales of antibiotic intermediates, as well as the impact of exchange rate fluctuations.

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 nine-month period ended September 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 *Delyba* 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 nine-month period ended September 30, 2022 totaled ¥193,765 million.

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

Pharmaceuticals

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

Research and development expenses in the pharmaceutical business for the nine-month period ended September 30, 2022 were ¥183,566 million.

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

Category	Brand Name, (Generic name), Development Code	Status
Psychiatry and neurology	(centanafadine) EB-1020	<U.S.> <ul style="list-style-type: none"> Phase II trial for the treatment of major depressive disorder was initiated in September 2022. Development for the treatment of smoking cessation was halted due to development strategy.
	<i>REXULTI</i> (brexpiprazole) OPC-34712 / OPC-34712 FUM	<U.S.> <ul style="list-style-type: none"> Development for the treatment of borderline personality disorder was halted due to development strategy. <Japan> <ul style="list-style-type: none"> Phase III trials of oral formulation for schizophrenia (once-weekly oral) were initiated in August 2022.
	(aripiprazole 2-month long-acting injection)	<U.S.> <ul style="list-style-type: none"> An application for the indication of schizophrenia and bipolar I disorder was filed in September 2022. <Europe> <ul style="list-style-type: none"> An application for the indication of schizophrenia was filed in June 2022.
	(deuterium-modified dextromethorphan, quinidine) AVP-786	<U.S.> <ul style="list-style-type: none"> Development for the treatment of intermittent explosive disorder and traumatic brain injury was halted due to development strategy.
	(ulotaront) SEP-363856	<U.S.> <ul style="list-style-type: none"> Phase II / III trial for the treatment of adjunctive major depressive disorder was initiated.
	OPC-64005	<Japan> <ul style="list-style-type: none"> Development for the treatment of major depressive disorder was halted due to development strategy.
Oncology	<i>LYTGOBI</i> (futibatinib) TAS-120	<Japan> <ul style="list-style-type: none"> An application for the indication of biliary tract cancer was filed in July 2022. <U.S.> <ul style="list-style-type: none"> Approval was granted for the indication of intrahepatic cholangiocarcinoma in September 2022. <Europe> <ul style="list-style-type: none"> An application for the indication of cholangiocarcinoma was filed.
	(zimberelimab + pimitespib) AB122 + TAS-116	<Japan> <ul style="list-style-type: none"> Phase I trial for the treatment of solid tumors*¹ was initiated in February 2022.
	(zimberelimab + pamufetinib) AB122 + TAS-115	<Japan> <ul style="list-style-type: none"> Phase I trial for the treatment of solid tumors*² was initiated in September 2022.
Oncology	<i>Arokaris</i> (fosnetupitant) Pro-NETU	<Japan> <ul style="list-style-type: none"> Approval was granted for the indication of chemotherapy-induced nausea and vomiting in March 2022.

Category	Brand Name, (Generic name), Development Code	Status
	<i>Jeslthy</i> (pimipitespib) TAS-116	<Japan> • Approval was granted for the indication of gastrointestinal stromal tumor in June 2022.
	TAS6417*3	<U.S. and Europe> • Currently in Phase I / II trial for the treatment of non-small cell lung cancer.
	<i>INQOVI</i> (decitabine, cedazuridine) ASTX727	<Europe> • An application for the indication of acute myeloid leukemia was filed in August 2022.
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	<Japan, U.S. and Europe> • Phase III trial for the treatment of IgA nephropathy was initiated in April 2022.
	<i>Lupkynis</i> (voclosporin)	<Europe> • Approval was granted for the indication of active lupus nephritis in September 2022.
Other categories	TAS5315	<Japan> • Phase II trial for the treatment of chronic spontaneous urticaria was initiated in June 2022.
	(quabodepistat) OPC-167832	<U.S.> • Phase II trial for tuberculosis was initiated in April 2022.

*1: pimipitespib combination cohort during the Phase I trial in Japan for zimberelimumab

*2: pamufetinib combination cohort during the Phase I trial in Japan for zimberelimumab

*3: 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 conduct research and development of scientifically based original products in order to maintain and promote the health of people. In the field of women's health, the Group was involved with a research paper suggesting that consumption of "γ-tocopherol, γ-tocotrienol, equol and calcium via a supplement containing these four ingredients" (γ-toco composite supplement) may alleviate subjective symptoms of premenstrual syndrome (PMS), experienced by approximately 70% of women*1. The research paper was published in the July 30, 2022 issue of *The Journal of Japan Society for Menopause and Women's Health**2. Moreover, amid the continuing various Group-wide initiatives and programs for contributing to a recycling society under the Otsuka Group Environmental Policy, the Group launched *POCARI SWEAT 250-milliliter Returnable Bottle* in July at selected stores using the circular shopping platform Loop. In addition, the Group launched *B240 Tablets* that contain lactic acid bacterium B240, a proprietary ingredient that supports maintenance of physical condition, in July through its own e-commerce portal. Although products under the *BODY MAINTÉ* brand contain lactic acid bacterium B240 to support day-to-day conditioning, the Group conceived of *B240 Tablets* as small, easy-to-swallow tablets to encourage ongoing consumption and is promoting initiatives that support people who wish to live health daily lives.

*1: Source: Otsuka Pharmaceutical survey of 1,000 Japanese women, aged 30 to 44; June-July 2021

*2: Title: "The effects of γ-tocopherol, γ-tocotrienol, equol and calcium supplementation on premenstrual symptoms: a randomized, double-blind, crossover trial"; Published in: *The Journal of Japan Society for Menopause and Women's Health* 29 (4) 578-587, 2022

Research and development expenses in the nutraceutical business for the nine-month period ended September 30, 2022 were ¥5,881 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 nine-month period ended September 30, 2022 were ¥485 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 nine-month period ended September 30, 2022 were ¥3,832 million.

(2) Consolidated Financial Position

1) Assets, Liabilities and Equity

(Millions of yen)

	As of December 31, 2021	As of September 30, 2022	Change
Current assets	1,049,389	1,180,406	131,017
Non-current assets	1,771,526	2,007,331	235,805
Total assets	2,820,915	3,187,738	366,823
Current liabilities	467,910	544,000	76,090
Non-current liabilities	307,815	309,317	1,501
Total liabilities	775,725	853,317	77,592
Total equity	2,045,189	2,334,421	289,231

a. Assets

Total assets as of September 30, 2022 were ¥3,187,738 million, an increase of ¥366,823 million compared to ¥2,820,915 million as of December 31, 2021. Current assets increased by ¥131,017 million, and non-current assets increased by ¥235,805 million.

(Current Assets)

Current assets as of September 30, 2022 were ¥1,180,406 million, an increase of ¥131,017 million compared to ¥1,049,389 million as of December 31, 2021. This was mainly due to increases in cash and cash equivalents by ¥66,606 million, trade and other receivables by ¥14,471 million, and inventories by ¥48,912 million.

(Non-current Assets)

Non-current assets as of September 30, 2022 were ¥2,007,331 million, an increase of ¥235,805 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 ¥27,770 million, goodwill by ¥68,501 million, intangible assets by ¥103,282 million (including a ¥48,370 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 ¥21,546 million.

b. Liabilities

Total liabilities as of September 30, 2022 were ¥853,317 million, an increase of ¥77,592 million compared to ¥775,725 million as of December 31, 2021. Current liabilities increased by ¥76,090 million, and non-current liabilities increased by ¥1,501 million.

(Current Liabilities)

Current liabilities as of September 30, 2022 were ¥544,000 million, an increase of ¥76,090 million compared to ¥467,910 million as of December 31, 2021. This was mainly due to increases in income taxes payable by ¥21,832 million and other current liabilities by ¥52,976 million, partially offset by a decrease in trade and other payables by ¥720 million.

(Non-current Liabilities)

Non-current liabilities as of September 30, 2022 were ¥309,317 million, an increase of ¥1,501 million compared to ¥307,815 million as of December 31, 2021. This was mainly due to increases in other financial liabilities by ¥3,384 million, net defined benefit liabilities by ¥2,063 million, deferred tax liabilities by ¥4,399 million and other non-current liabilities by ¥5,540 million, partially offset by decreases in bonds and borrowings by ¥7,224 million and contract liabilities by ¥6,480 million.

c. Equity

Total equity as of September 30, 2022 was ¥2,334,421 million, an increase of ¥289,231 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 ¥227,274 million as a result of exchange rate fluctuations, and an increase in retained earnings by ¥58,199 million which consisted of profit attributable to owners of the Company of ¥111,030 million net of dividend payments of ¥54,251 million.

2) Cash Flows

Cash and cash equivalents as of September 30, 2022 were ¥477,290 million, an increase of ¥66,606 million compared to the balance as of December 31, 2021. For the nine-month period ended September 30, 2022, net cash flows provided by operating activities were ¥171,071 million, while net cash flows used in investing activities were ¥60,410 million mainly as a result of investments in the pharmaceutical business toward sustainable growth. Net cash flows used in financing activities were ¥84,018 million as a result of repayments of borrowings and lease liabilities and ¥55,474 million of dividends paid.

Thus, cash and cash equivalents were increased to ¥477,290 million as operating cash inflows exceeded the total cash outflows from investing and financing activities, further augmented by the effect of ¥39,963 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 nine-month period ended September 30, 2022:

Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥171,071 million, a decrease of ¥26,138 million compared to the figure for the nine-month period ended September 30, 2021. Cash flows provided by operating activities for the nine-month period ended September 30, 2022 mainly consisted of ¥145,999 million of profit before tax, adjusted for ¥69,237 million of depreciation and amortization expenses, ¥30,697 million of impairment losses and reversal of impairment losses, ¥35,177 million of finance income, ¥24,469 million decrease in trade and other receivables, ¥42,164 million decrease in trade and other payables and ¥31,268 million of income taxes paid. The decrease of ¥26,138 million in inflows was primarily due to a ¥20,308 million decrease of profit before tax, a ¥9,699 million increase in outflow to inventories and

a ¥12,859 million increase in outflow to trade and other payables, partially offset by a ¥18,611 million decrease of income taxes paid.

Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥60,410 million, an increase in outflows of ¥27,401 million compared to the figure for the nine-month period ended September 30, 2021. Cash flows used in investing activities for the nine-month period ended September 30, 2022 mainly consisted of ¥44,900 million of payments for acquisition of property, plant and equipment including an investment in the Osaka Pharmaceutical Research Institute, ¥40,596 million of payments for acquisition of intangible assets including an asset acquisition of TAS6417 from Cullinan Pearl, ¥34,223 million of proceeds from sales and redemption of investments and ¥17,972 million of payments for acquisition of investments. The increase of ¥27,401 million in outflows was primarily due to a ¥27,752 million increase in payments for acquisition of intangible assets including an asset acquisition of TAS6417 in the pharmaceutical business, and a ¥27,792 million increase in outflows to time deposits, partially offset by a ¥16,805 million increase of proceeds from sales and redemption of investments.

Cash Flows from Financing Activities

Net cash flows used in financing activities were ¥84,018 million, an increase in outflows of ¥293 million compared to the figure for the nine-month period ended September 30, 2021. Cash flows used in financing activities for the nine-month period ended September 30, 2022 mainly consisted of ¥17,524 million of repayments of long-term borrowings, ¥14,740 million of repayments of lease liabilities and ¥55,474 million of dividends paid.

(3) Forecast for Consolidated Operating Results

In response to the consolidated operating results for the nine-month period ended September 30, 2022, the Company revised its consolidated operating results forecast for the fiscal year ending December 31, 2022 that it released on July 29, 2022 as follows:

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

	Previous forecast (A)	Revised forecast (B)	Amount of change (B) – (A)	Change (%)	(Reference) FY2021
Revenue	1,670,000	1,710,000	40,000	2.4	1,498,276
Business profit before research and development expenses	430,000	435,000	5,000	1.2	389,427
Business profit	160,000	160,000	0	0.0	157,127
Operating profit	152,000	142,000	(10,000)	(6.6)	154,497
Profit before tax	177,000	172,000	(5,000)	(2.8)	163,638
Profit for the year	138,000	134,000	(4,000)	(2.9)	129,209
Profit attributable to owners of the Company	135,000	131,000	(4,000)	(3.0)	125,463
Basic earnings per share (Yen)	248.82	241.46			231.32

(Millions of yen)

Research and development expenses	270,000	275,000	5,000	1.9	232,299
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(Note) Forecast exchange rates are as follows:

	Previous forecast	Revised forecast
USD	125 yen	131 yen
EUR	136 yen	137 yen

Revenue for the fiscal year ending December 31, 2022 is expected to exceed the previously announced forecast owing to brisk sales of the four global products (*ABILIFY MAINTENA*, *REXULTI/RXULTI*, *JINARC/JYNARQUE* and *LONSURF*), as well as the impact of exchange rate fluctuations. Furthermore, business profit is expected to be in line with the previous forecast due to an increase in revenue excluding exchange rate fluctuations and due to controls imposed on selling, general and administrative expenses, and despite increases in cost of sales, selling, general and administrative expenses, and research and development expenses, along with a greater impact of exchange rate fluctuations on the elimination of unrealized gains on inventories in the pharmaceutical business.

Meanwhile, 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 impact of impairment losses having been recorded with respect to property, plant and equipment and intangible assets (mainly trademarks, distribution rights and others) of Japanese and UK subsidiaries pertaining to the Group's medical devices business during the nine-month period ended September 30, 2022.

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 September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	410,684	477,290
Trade and other receivables	380,191	394,663
Inventories	180,350	229,262
Income taxes receivable	8,543	4,218
Other financial assets	20,074	17,184
Other current assets	48,036	57,645
Subtotal	1,047,880	1,180,264
Assets held for sale	1,508	142
Total current assets	1,049,389	1,180,406
Non-current assets		
Property, plant and equipment	487,089	514,860
Goodwill	295,735	364,237
Intangible assets	522,662	625,944
Investments accounted for using the equity method	227,790	249,336
Other financial assets	173,956	183,100
Deferred tax assets	31,936	50,983
Other non-current assets	32,355	18,869
Total non-current assets	1,771,526	2,007,331
Total assets	2,820,915	3,187,738

(Millions of yen)

	As of December 31, 2021	As of September 30, 2022
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	170,103	169,382
Bonds and borrowings	32,877	32,856
Lease liabilities	17,096	17,710
Other financial liabilities	1,988	3,430
Income taxes payable	10,490	32,323
Provisions	9,542	9,391
Contract liabilities	12,458	12,626
Other current liabilities	213,302	266,278
Subtotal	467,859	544,000
Liabilities directly associated with assets held for sale	50	-
Total current liabilities	467,910	544,000
Non-current liabilities		
Bonds and borrowings	102,754	95,530
Lease liabilities	59,726	59,462
Other financial liabilities	24,815	28,199
Net defined benefit liabilities	14,075	16,139
Provisions	1,358	1,440
Contract liabilities	57,771	51,290
Deferred tax liabilities	27,560	31,959
Other non-current liabilities	19,753	25,293
Total non-current liabilities	307,815	309,317
Total liabilities	775,725	853,317
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	506,724	506,470
Treasury shares	(45,572)	(44,858)
Retained earnings	1,482,197	1,540,397
Other components of equity	(14,046)	213,227
Total equity attributable to owners of the Company	2,010,994	2,296,927
Non-controlling interests	34,195	37,493
Total equity	2,045,189	2,334,421
Total liabilities and equity	2,820,915	3,187,738

(2) Condensed Interim Consolidated Statements of Income

(Millions of yen)

	FY2021 (Nine-month period ended September 30, 2021)	FY2022 (Nine-month period ended September 30, 2022)
Revenue	1,107,417	1,266,119
Cost of sales	(358,668)	(427,016)
Gross profit	748,749	839,103
Selling, general and administrative expenses	(439,009)	(523,338)
Share of profit of investments accounted for using the equity method	8,644	3,696
Research and development expenses	(162,521)	(193,765)
Impairment losses	(5,051)	(30,697)
Other income	10,571	20,812
Other expenses	(3,252)	(961)
Operating profit	158,130	114,848
Finance income	11,056	35,177
Finance expenses	(2,878)	(4,026)
Profit before tax	166,308	145,999
Income tax expenses	(36,275)	(32,053)
Profit for the period	130,033	113,945
Attributable to:		
Owners of the Company	126,648	111,030
Non-controlling interests	3,384	2,914
Profit for the period	130,033	113,945
Earnings per share:		
Basic earnings per share (Yen)	233.50	204.65
Diluted earnings per share (Yen)	233.34	204.63

(3) Condensed Interim Consolidated Statements of Comprehensive Income

	(Millions of yen)	
	FY2021 (Nine-month period ended September 30, 2021)	FY2022 (Nine-month period ended September 30, 2022)
Profit for the period	130,033	113,945
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	1,804	127
Financial assets measured at fair value through other comprehensive income	(10,210)	5,727
Share of other comprehensive income of investments accounted for using the equity method	(190)	96
Subtotal	(8,596)	5,951
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	58,969	201,993
Cash flow hedges	2	(2)
Share of other comprehensive income of investments accounted for using the equity method	9,262	22,473
Subtotal	68,234	224,464
Total other comprehensive income	59,638	230,416
Total comprehensive income for the period	189,671	344,361
Attributable to:		
Owners of the Company	185,621	339,724
Non-controlling interests	4,049	4,637
Total comprehensive income for the period	189,671	344,361

(4) Condensed Interim Consolidated Statements of Changes in Equity
FY2021 (Nine-month period ended September 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	—	—	—	126,648	—	—
Other comprehensive income	—	—	—	—	1,850	(10,393)
Comprehensive income for the period	—	—	—	126,648	1,850	(10,393)
Purchase of treasury shares	—	—	(1)	—	—	—
Dividends	—	—	—	(54,236)	—	—
Share-based payment transactions	—	279	210	—	—	—
Changes in ownership interests in subsidiaries that do not result in loss of control	—	(0)	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	3,344	(1,850)	(1,494)
Total transactions with owners	—	278	209	(50,891)	(1,850)	(1,494)
Balance as of September 30, 2021	81,690	506,574	(45,571)	1,478,400	—	31,409

	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	—	—	—	126,648	3,384	130,033
Other comprehensive income	67,514	2	58,973	58,973	664	59,638
Comprehensive income for the period	67,514	2	58,973	185,621	4,049	189,671
Purchase of treasury shares	—	—	—	(1)	—	(1)
Dividends	—	—	—	(54,236)	(1,747)	(55,984)
Share-based payment transactions	—	—	—	489	—	489
Changes in ownership interests in subsidiaries that do not result in loss of control	—	—	—	(0)	—	(0)
Transfer from other components of equity to retained earnings	—	—	(3,344)	—	—	—
Total transactions with owners	—	—	(3,344)	(53,748)	(1,747)	(55,495)
Balance as of September 30, 2021	(68,252)	(2)	(36,845)	1,984,248	33,359	2,017,608

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	—	—	—	111,030	—	—
Other comprehensive income	—	—	—	—	255	5,813
Comprehensive income for the period	—	—	—	111,030	255	5,813
Purchase of treasury shares	—	—	(0)	—	—	—
Dividends	—	—	—	(54,251)	—	—
Share-based payment transactions	—	(254)	714	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	1,419	(255)	(1,163)
Total transactions with owners	—	(254)	713	(52,831)	(255)	(1,163)
Balance as of September 30, 2022	81,690	506,470	(44,858)	1,540,397	—	33,282

Equity attributable to owners of the Company

	Other components of equity			Total	Non-controlling interests	Total equity
	Exchange differences on translation of foreign operations	Cash flow hedges	Total			
Balance as of January 1, 2022	(42,673)	(6)	(14,046)	2,010,994	34,195	2,045,189
Profit for the period	—	—	—	111,030	2,914	113,945
Other comprehensive income	222,627	(2)	228,693	228,693	1,722	230,416
Comprehensive income for the period	222,627	(2)	228,693	339,724	4,637	344,361
Purchase of treasury shares	—	—	—	(0)	—	(0)
Dividends	—	—	—	(54,251)	(1,338)	(55,589)
Share-based payment transactions	—	—	—	459	—	459
Transfer from other components of equity to retained earnings	—	—	(1,419)	—	—	—
Total transactions with owners	—	—	(1,419)	(53,792)	(1,338)	(55,130)
Balance as of September 30, 2022	179,953	(8)	213,227	2,296,927	37,493	2,334,421

(5) Condensed Interim Consolidated Statements of Cash Flows

(Millions of yen)

	FY2021 (Nine-month period ended September 30, 2021)	FY2022 (Nine-month period ended September 30, 2022)
Cash flows from operating activities		
Profit before tax	166,308	145,999
Depreciation and amortization expenses	62,301	69,237
Impairment losses and reversal of impairment losses	5,051	30,697
Share of profit of investments accounted for using the equity method	(8,644)	(3,696)
Finance income	(11,056)	(35,177)
Finance expenses	2,878	4,026
Decrease (increase) in inventories	3,858	(5,840)
Decrease in trade and other receivables	31,025	24,469
Decrease in trade and other payables	(29,304)	(42,164)
Others	18,448	7,526
Subtotal	<u>240,865</u>	<u>195,078</u>
Interest and dividends received	8,269	9,370
Interest paid	(2,044)	(2,108)
Income taxes paid	(49,880)	(31,268)
Net cash flows provided by operating activities	<u>197,210</u>	<u>171,071</u>
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	1,672	3,362
Payments for acquisition of property, plant and equipment	(36,643)	(44,900)
Payments for acquisition of intangible assets	(12,843)	(40,596)
Proceeds from sales and redemption of investments	17,417	34,223
Payments for acquisition of investments	(20,802)	(17,972)
Proceeds from sales of subsidiaries	-	8,323
Payments for acquisition of subsidiaries	(8,036)	-
Decrease (increase) in time deposits	24,416	(3,376)
Others	1,810	526
Net cash flows used in investing activities	<u>(33,009)</u>	<u>(60,410)</u>
Cash flows from financing activities		
Purchase of treasury shares	(1)	(0)
Change in short-term borrowings, net	(211)	2,660
Proceeds from long-term borrowings	430	1,061
Repayments of long-term borrowings	(14,122)	(17,524)
Repayments of lease liabilities	(13,834)	(14,740)
Dividends paid	(55,984)	(55,474)
Others	(0)	-
Net cash flows used in financing activities	<u>(83,724)</u>	<u>(84,018)</u>
Increase in cash and cash equivalents	80,477	26,642
Cash and cash equivalents at the beginning of the period	356,851	410,684
Effect of exchange rate changes on cash and cash equivalents	11,349	39,963
Cash and cash equivalents at the end of the period	<u>448,678</u>	<u>477,290</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 (Nine-month period ended September 30, 2021)

(Millions of yen)

	Reportable segment					Adjustments *	Consolidated
	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	720,974	280,038	24,098	82,306	1,107,417	—	1,107,417
Intersegment revenue or transfers	—	33	17	28,445	28,496	(28,496)	—
Total	720,974	280,072	24,115	110,752	1,135,914	(28,496)	1,107,417
Segment profit	127,955	45,789	5,781	12,225	191,751	(33,620)	158,130

* Adjustments to segment profit of ¥(33,620) million include intersegment eliminations of ¥205 million, unallocated corporate expenses of ¥(34,570) million and other income of ¥743 million. Corporate expenses are incurred in administrative departments such as headquarters.

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

(Millions of yen)

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

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

Impairment of Assets

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

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

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 ¥48,370 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.