Kyowa Kirin Co., Ltd.

Consolidated Financial Summary (IFRS)
Fiscal 2022

(January 1, 2022 – December 31, 2022)

This document is an English translation of the Japanese-language original.

SUMMARY OF CONSOLIDATED FINANCIAL STATEMENTS (IFRS)
for Fiscal Year Ended December 31, 2022
(The twelve-month period from January 1, 2022 to December 31, 2022)

February 7, 2023

Company Name: Kyowa Kirin Co., Ltd.
Listed Exchanges: 1st Section of the Tokyo Stock Exchange
Stock Code: 4151
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Scheduled date of Ordinary General Meeting of Shareholders: March 24, 2023
Scheduled start date of dividend payment: March 27, 2023
Scheduled date of submission of Annual Securities Report: March 9, 2023
Appendix materials to accompany the annual financial report: Yes
FY2022 earnings presentation meeting: Yes (for institutional investors and securities analysts)

(Millions of yen rounded off)

1. Consolidated Financial Results for the Fiscal Year Ended December 31, 2022 (from January 1, 2022 to December 31, 2022)

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

	Revenue		Core operating profit		Profit before tax		Profit	
Fiscal year ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
December 31, 2022	398,371	13.1	86,697	32.0	67,572	12.5	53,573	2.3
December 31, 2021	352,246	10.6	65,685	9.6	60,050	14.9	52,347	11.3

Total comprehensive income: Fiscal year ended December 31, 2022: ¥50,654 million; (19.3)%
Fiscal year ended December 31, 2021: ¥62,751 million; 43.9%

Note: Core operating profit was calculated by deducting “selling, general and administrative expenses” and “research and development expenses” from “gross profit,” and adding “share of profit (loss) of investments accounted for using equity method” to the amount.

	Profit attributable to owners of parent		Basic earnings per share	Diluted earnings per share	Return on equity attributable to owners of parent	Profit before tax to total assets ratio
Fiscal year ended	Millions of yen	%	Yen	Yen	%	%
December 31, 2022	53,573	2.3	99.68	99.66	7.1	7.3
December 31, 2021	52,347	11.3	97.43	97.39	7.3	7.0

(Reference) Share of profit (loss) of investments accounted for using equity method:
Fiscal year ended December 31, 2022: ¥4,323 million;
Fiscal year ended December 31, 2021: ¥4,575 million

(2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent to total assets	Equity attributable to owners of parent per share
As of	Millions of yen	Millions of yen	Millions of yen	%	Yen
December 31, 2022	939,881	762,826	762,826	81.2	1,419.27
December 31, 2021	921,872	737,162	737,162	80.0	1,371.90

(3) Consolidated cash flows

	Net cash provided by (used in) operating activities	Net cash provided by (used in) investing activities	Net cash provided by (used in) financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Millions of yen	Millions of yen	Millions of yen	Millions of yen
December 31, 2022	48,672	(17,185)	(29,032)	339,194
December 31, 2021	86,548	(11,363)	(28,446)	335,084

2. Dividends

	Dividends per share					Total dividend amount	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to owners of parent (consolidated)
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
Fiscal year ended December 31, 2021	–	23.00	–	23.00	46.00	24,717	43.2	3.4
Fiscal year ended December 31, 2022	–	24.00	–	27.00	51.00	25,799	38.9	3.7
Fiscal year ending December 31, 2023 (Forecast)	–	27.00	–	27.00	54.00		39.9	

Note: The figure of “dividend payout ratio (consolidated)” indicates the dividend payout ratio based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting “other income,” “other expenses” and the related “income tax expense” from “profit”) by the average number of shares during the period).

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2023 (from January 1, 2023 to December 31, 2023)

(Percentages indicate year-on-year changes.)

	Revenue		Core operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full year	426,000	6.9	88,000	1.5	94,000	39.1	76,000	41.9	76,000	41.9	141.40

*** Notes**

(1) Changes to significant subsidiaries during the period (Changes of specified subsidiaries resulting in changes in the scope of consolidation during the period under review): No

(2) Changes in accounting policies, and accounting estimates:

a. Changes in accounting policies required by IFRS: No

b. Changes in accounting policies other than a. above: No

c. Changes in accounting estimates: No

(3) Number of shares issued (ordinary shares)

a. Number of shares issued (including treasury shares)

As of December 31, 2022	540,000,000 shares
As of December 31, 2021	540,000,000 shares

b. Number of treasury shares

As of December 31, 2022	2,521,197 shares
As of December 31, 2021	2,671,817 shares

c. Average number of shares during the period

FY ended December 31, 2022	537,431,734 shares
FY ended December 31, 2021	537,272,070 shares

(Reference)
Non-Consolidated Results for the Fiscal Year Ended December 31, 2022 (Japanese GAAP)
(from January 1, 2022 to December 31, 2022)

(1) Non-consolidated operating results *(Percentages indicate year-on-year changes.)*

	Net sales		Operating profit		Ordinary profit		Profit	
Fiscal year ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
December 31, 2022	253,790	6.8	40,634	63.8	37,287	5.8	31,047	(53.2)
December 31, 2021	237,590	(6.1)	24,802	(49.0)	35,228	(28.9)	66,366	112.4

	Basic earnings per share	Diluted earnings per share
Fiscal year ended	Yen	Yen
December 31, 2022	57.77	57.75
December 31, 2021	123.52	123.47

(2) Non-consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Millions of yen	Millions of yen	%	Yen
December 31, 2022	806,058	601,918	74.6	1,119.48
December 31, 2021	794,087	596,921	75.1	1,110.13

(Reference) Equity: As of December 31, 2022: ¥601,699 million; As of December 31, 2021: ¥596,507 million

* These financial results reports are exempt from audit conducted by certified public accountants or an audit corporation.

* Notice regarding the appropriate use of the earnings forecasts and other special comments
  The forward-looking statements, including earnings forecasts, contained in these materials are based on the information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons. For more information regarding our suppositions that form the assumptions for the earnings forecasts, please see pages 18 and 19 of the attachment, “(5) Outlook for Fiscal 2023” in “1. Summary of Business Performance and Financial Position.”

Attachment Index

1. Summary of Business Performance and Financial Position

< Overview of business >

Amid enormous and complex changes in the business environment, including geopolitical risks on top of the prolonged effect from COVID-19, among other factors, the Group carried out activities such as strengthening research and development, production, and logistics, and collecting and providing information with the aim of providing drugs that satisfy unmet medical needs.

In 2022, the Group has been proceeding with initiatives for the second year of the FY2021-2025 Medium Term Business Plan aimed at realizing the Group's vision for 2030: Kyowa Kirin will realize the successful creation and delivery of life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

Despite some restrictions on business activities due to COVID-19, the Group continued to steadily achieve growth from global strategic products such as Crysvita and POTELIGEO. On the other hand, while adapting to extreme changes to the external environment, the Group took urgent steps to take part in global collaborations and establish the growth strategies for delivering the Company's pharmaceuticals to as many needy patients as possible. In the established medicines business[*1] in Europe, the Group entered into an agreement concerning joint-venture collaboration with German company Grünenthal GmbH[*2] to continually deliver those medicines to the patients needing them.

Regarding the next-generation strategic products, the Group is steadily developing KHK4083 for the therapeutic areas of immunology/allergy through collaboration with Amgen Inc. of the United States. On the other hand, the Group decided to discontinue the development of Kyowa Kirin's proprietary KW-6356 in the central nervous system field, and to also discontinue joint development with MEI Pharma of ME-401 in the oncology field outside Japan. As for our initial stage development products, such as bispecific antibodies developed using our proprietary technologies, we are taking steps to advance research and development with the expectation that they will become a growth platform in the medium to long term. Through measures such as constructing a new biopharmaceutical API manufacturing facility and a new multipurpose facility relating to quality assurance, which will adopt cutting-edge facilities, we are aiming to strengthen our competitiveness as Japan's global specialty pharmaceutical company.

Regarding initiatives aimed at both contributing to the realization of a sustainable society and achieving business growth, we have formulated the "Kyowa Kirin Group Policy for Access to Medicines" and are striving to respond to medical needs, centered on patients. In addition, we have established the Kyowa Kirin Group Human Rights Policy, which forms the basis for the Group's corporate activities concerning business and human rights.

*1 This type of business mainly handles patent-expired branded drugs and generics.

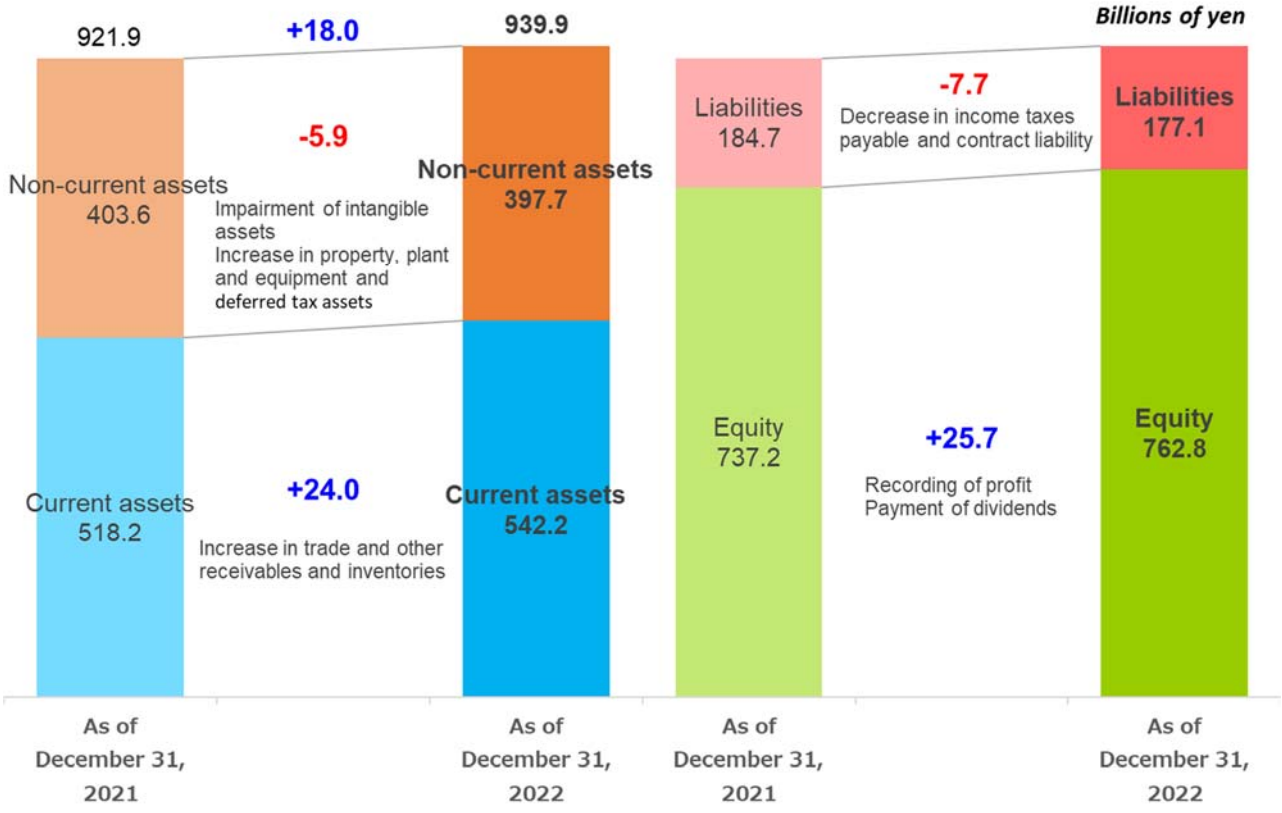
*2 Customary approvals and clearances, including anti-trust and works councils as legally required, will need to be obtained as a condition for the agreement to take effect.

(1) Summary of Consolidated Financial Position for Fiscal 2022

(Billions of yen)

	As of December 31, 2021	As of December 31, 2022	Year-on-year change
Assets	921.9	939.9	18.0
Non-current assets	403.6	397.7	(5.9)
Current assets	518.2	542.2	24.0
Liabilities	184.7	177.1	(7.7)
Equity	737.2	762.8	25.7
Ratio of equity attributable to owners of parent to total assets (%)	80.0%	81.2%	1.2%

- Assets as of December 31, 2022, were ¥939.9 billion, an increase of ¥18.0 billion compared to the end of the previous fiscal year.
  - Non-current assets decreased by ¥5.9 billion compared to the end of the previous fiscal year, to ¥397.7 billion, due mainly to impairment of intangible assets, which offset increases in property, plant and equipment and deferred tax assets.
  - Current assets increased by ¥24.0 billion compared to the end of the previous fiscal year, to ¥542.2 billion, due mainly to increases in trade and other receivables and inventories.
- Liabilities as of December 31, 2022, were ¥177.1 billion, a decrease of ¥7.7 billion compared to the end of the previous fiscal year, due mainly to decreases in income taxes payable and contract liabilities.
- Equity as of December 31, 2022, was ¥762.8 billion, an increase of ¥25.7 billion compared to the end of the previous fiscal year, due mainly to the recording of profit attributable to owners of parent, despite a decrease due to the payment of dividends, etc. As a result, the ratio of equity attributable to owners of parent to total assets was 81.2%, an increase of 1.2 percentage points compared to the end of the previous fiscal year.



(2) Summary of Business Performance in Fiscal 2022

1) Overview of results

The Group now applies the International Financial Reporting Standards (“IFRS”) in line with its policy of expanding business globally, and adopts “core operating profit” as a level of profit that shows the recurring profitability from operating activities. Core operating profit is calculated by deducting “selling, general and administrative expenses” and “research and development expenses” from “gross profit,” and adding “share of profit (loss) of investments accounted for using equity method” to the amount.

(Billions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change	Rate of change (%)
Revenue	352.2	398.4	46.1	13.1%
Core operating profit	65.7	86.7	21.0	32.0%
Profit before tax	60.1	67.6	7.5	12.5%
Profit attributable to owners of parent	52.3	53.6	1.2	2.3%

< Average exchange rates for each period >

Currency	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change
USD (USD/¥)	¥109	¥130	Up ¥21
GBP (GBP/¥)	¥150	¥161	Up ¥11
EUR (EUR/¥)	¥130	¥137	Up ¥7

For the fiscal year ended December 31, 2022, revenue was ¥398.4 billion (up 13.1% compared to the previous fiscal year) and core operating profit was ¥86.7 billion (up 32.0%). Profit attributable to owners of parent was ¥53.6 billion (up 2.3%).

- The increase in revenue was the result of growth of global strategic products in North America and EMEA and a rise in revenue from technology out-licensing, despite lower revenue in Japan. The positive effect on revenue from foreign exchange was ¥30.1 billion.
- Core operating profit rose, despite increases in selling, general and administrative expenses and research and development expenses, due to higher gross profit resulting from an increase in overseas revenue and a rise in revenue from technology out-licensing. The positive effect on core operating profit from foreign exchange was ¥11.0 billion.
- Profit attributable to owners of parent increased as a result of an increase in finance income in addition to an increase in core operating profit, despite an increase in income taxes in addition to an increase in other expenses due to increased impairment losses.

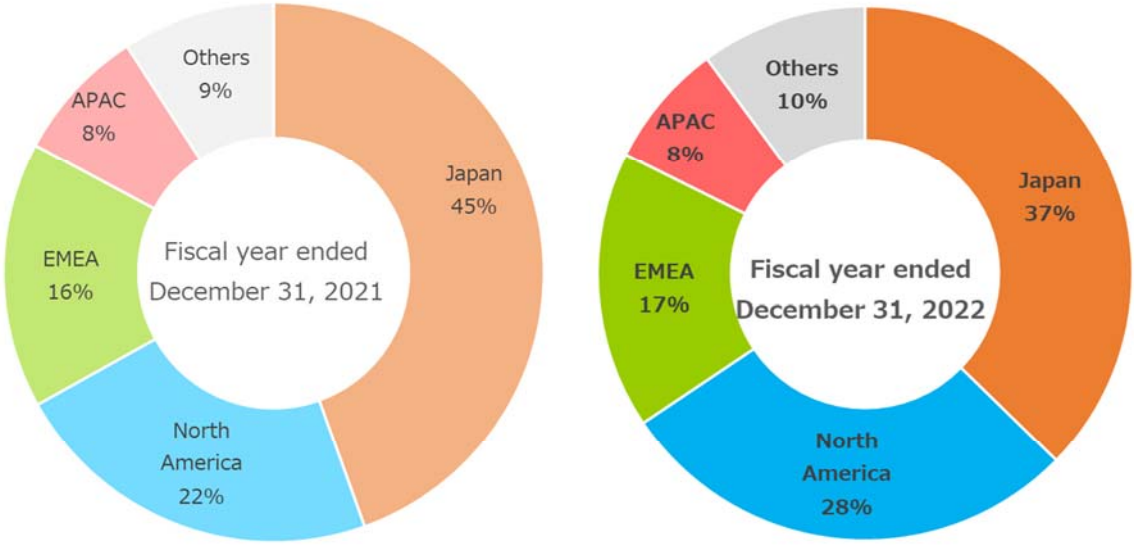
2) Revenue by regional control function

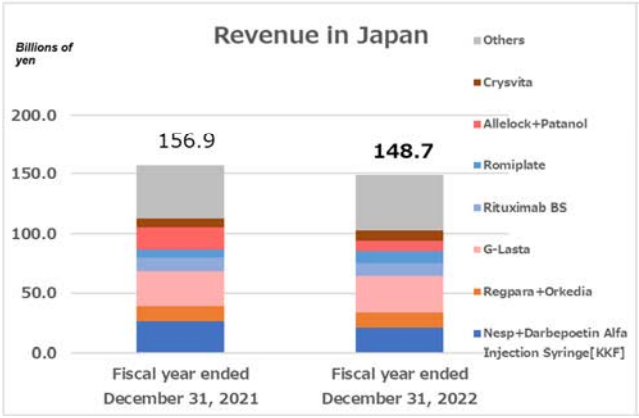
(Billions of yen)

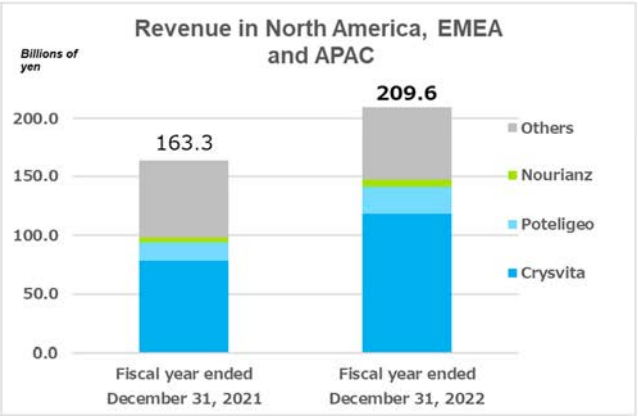
	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change	Rate of change (%)
Japan	156.9	148.7	(8.2)	(5.2)%
North America	78.8	112.6	33.8	42.9%
EMEA	56.1	66.9	10.8	19.2%
APAC	28.4	30.1	1.8	6.3%
Others	32.1	40.1	8.0	24.8%
Total consolidated revenue	352.2	398.4	46.1	13.1%

Notes:
1. Revenue by regional control function is classified based on consolidated revenue from products of regional control functions in the One Kyowa Kirin (OKK) matrix global management structure, which combines a regional organization based on four regions of Japan, North America, EMEA and APAC, a functional organization, and a product organization (product franchises).
2. EMEA consists of Europe, the Middle East, Africa, etc.
3. Others consists of revenue from technology out-licensing, original equipment manufacturing, etc.

Composition of revenue by regional control function







< Revenue of major products (Japan) >

(Billions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change	Rate of change (%)
Patanol	10.7	2.8	(7.9)	(73.9)%
Darbepoetin Alfa Injection Syringe [KKF]	22.3	17.6	(4.7)	(20.9)%
Duvroq	2.6	6.6	4.0	155.8%
Romiplate	7.3	10.4	3.2	43.3%
G-Lasta	29.4	31.1	1.7	5.7%
Crysvita	7.2	8.9	1.7	23.5%

- Revenue in Japan decreased year on year due to the significant decrease in revenue from Patanol, anti-allergy eye drops, in addition to the impact of the reductions in drug price standards implemented in April 2021 and April 2022, despite the growth in sales of new product groups, such as Duvroq, a treatment for renal anemia.

・ Revenue from Patanol, anti-allergy eye drops, decreased due to the release of a generic in December 2021.

・ Revenue from Darbepoetin Alfa Injection Syringe [KKF] decreased due to the impact of the reductions in drug price standards and the market penetration of rival products.

・ Revenue from Duvroq, a treatment for renal anemia, has been growing since its launch in August 2020.

・ Revenue from ROMIPLATE, a treatment for chronic idiopathic thrombocytopenic purpura, increased due to the impact in the previous fiscal year from adjustments of shipments to distributors (June 2020 to March 2021).

・ Revenue from G-Lasta, an agent for decreasing the incidence of febrile neutropenia, has been growing. The automated injection device G-Lasta Subcutaneous Injection 3.6 mg BodyPod was launched in December 2022.

・ Revenue from Crysvita, a treatment for FGF23-related diseases, has been growing since its launch in December 2019.

< Revenue of major products (overseas) >

(Billions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change	Rate of change (%)
Crysvita	78.3	118.2	39.9	50.9%
Poteligeo	15.3	22.3	7.0	45.9%
Nourianz	4.5	6.5	1.9	42.7%
Abstral	8.5	6.9	(1.6)	(19.1)%
Regpara	7.4	3.9	(3.5)	(46.6)%
Gran	6.3	8.2	1.9	29.8%

- Revenue in North America increased year on year due to the growth of global strategic products.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing since its launch in 2018.
  - Revenue from POTELIGEO, an anticancer agent, has been growing.
  - Revenue from NOURIANZ™ (product name in Japan: NOURIAST), an antiparkinsonian agent, has been growing since its launch in October 2019.

- Revenue in EMEA increased year on year due to the growth of global strategic products.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing as the number of countries where it has been released has been increasing since its launch in 2018. Approval for the extended indication for tumor induced osteomalacia (TIO) was acquired from the European Commission (EC) in August 2022, and sales were launched in Germany and other countries.
  - Revenue from POTELIGEO, an anticancer agent, has been growing as the number of countries where it has been released has been increasing since its launch in June 2020.
  - Revenue from Abstral, a treatment for cancer pain, decreased due to the impact of the market penetration of generics.

- Revenue in APAC increased year on year.
  - Revenue from REGPARA, a treatment for secondary hyperparathyroidism, declined after it became subject to China's centralized governmental purchasing system* in October 2021.
    * Volume-Based Procurement (VBP) program that was introduced in 2018 for reducing healthcare cost in China. Even though only 2 to 5 companies are selected as suppliers through a tender, drug prices are dramatically dropped down.
  - Revenue from Gran, a neutropenia treatment drug, has been growing particularly in South Korea.

< Other revenue >

- Revenue from Others increased year on year.
  - Technology out-licensing increased due to the recognition of revenue of upfront payment of USD400 million over a certain period in conjunction with the conclusion of an agreement in 2021 with Amgen Inc. to jointly develop and commercialize KHK4083, anti-OX40 fully human monoclonal antibody for the treatment of atopic dermatitis, in addition to an increase in royalties revenue from AstraZeneca in relation to benralizumab.

3) Core operating profit

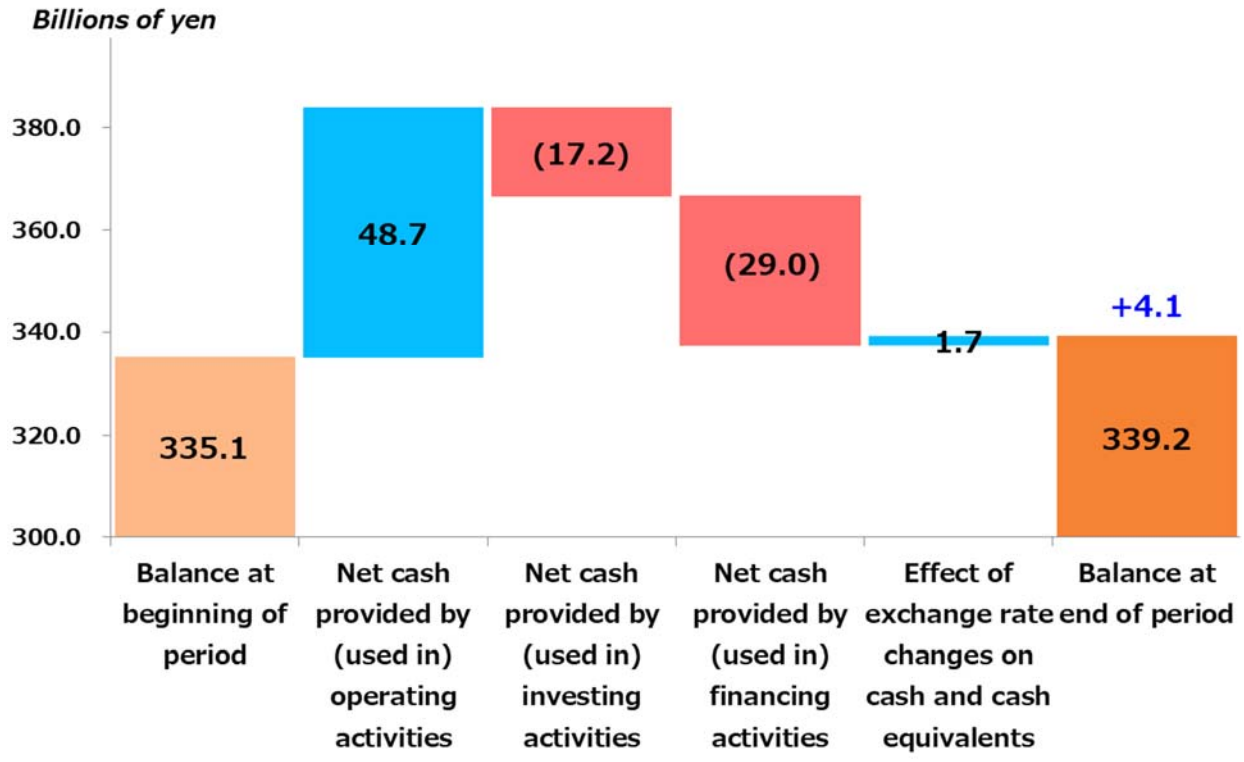
- Core operating profit increased compared to the previous fiscal year due mainly to an increase in gross profit due to increases in revenue from U.S. and Europe, mainly from global strategic products, and in revenue from technology out-licensing, despite increases in research and development expenses mainly regarding progress in development of next-generation strategic products, in addition to increases in selling, general and administrative expenses related to investments in human resources and in IT/digital platform aimed at maximizing the value of global strategic products and rapidly establishing competitive global business bases. The positive effect on core operating profit from foreign exchange was ¥11.0 billion.

(3) Cash Flow Summary for Fiscal 2022

(Billions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022	Year-on-year change	Rate of change (%)
Net cash provided by (used in) operating activities	86.5	48.7	(37.9)	(43.8)%
Net cash provided by (used in) investing activities	(11.4)	(17.2)	(5.8)	51.2%
Net cash provided by (used in) financing activities	(28.4)	(29.0)	(0.6)	2.1%
Cash and cash equivalents at beginning of period	287.0	335.1	48.1	16.7%
Cash and cash equivalents at end of period	335.1	339.2	4.1	1.2%

- Cash and cash equivalents as of December 31, 2022 were ¥339.2 billion, an increase of ¥4.1 billion compared to the balance of ¥335.1 billion as of December 31, 2021.
  The main contributing factors affecting cash flow during the current fiscal year were as follows:
- Net cash provided by operating activities was ¥48.7 billion, compared with net cash provided by operating activities of ¥86.5 billion in the previous fiscal year. Major inflows included impairment losses of ¥18.0 billion in addition to profit before tax of ¥67.6 billion and depreciation and amortization of ¥18.5 billion. Major outflows included income taxes paid of ¥22.6 billion and decrease (increase) in inventories of ¥8.9 billion.
- Net cash used in investing activities was ¥17.2 billion, compared with net cash used in investing activities of ¥11.4 billion in the previous fiscal year. Major outflows included purchase of property, plant and equipment of ¥15.6 billion and purchase of intangible assets of ¥13.1 billion. On the other hand, major inflows included revenue from advance receipt from sale of investment securities of ¥4.2 billion, proceeds from redemption of bonds of subsidiaries and associates of ¥4.0 billion, and proceeds from sale of investment securities of ¥3.7 billion.
- Net cash used in financing activities was ¥29.0 billion, compared with net cash used in financing activities of ¥28.4 billion in the previous fiscal year. Major outflows included dividends paid of ¥25.3 billion.



(4) Research and Development Activities

The Group continuously and actively invests resources in research and development activities. We aim to advance both a technological pillar that can build a platform for applying various modalities and discovering innovative drugs and a disease pillar that continues to provide “only-one value drugs” for diseases for which there are no effective treatments while utilizing the disease science accumulated by the Group thus far, build a highly competitive pipeline, and provide new drugs with life-changing value worldwide.

For the fiscal year ended December 31, 2022, the Group’s research and development expenses totaled ¥62.9 billion, and our progress in the respective disease fields of our main late-stage development products is as follows. (“◆” indicates the progress made during the fourth quarter of fiscal 2022.)

Nephrology

KHK7580 (product name in Japan: ORKEDIA)

- In July 2022, we applied for approval for marketing as its indication for treatment of secondary hyperparathyroidism in China.
- ◆ In November 2022, we applied for approval for marketing as its indication for treatment of secondary hyperparathyroidism in South Korea.

KHK7791 (generic name: Tenapanor Hydrochloride)

- ◆ In October 2022, we applied for approval for improvement of hyperphosphatemia in chronic kidney disease patients on dialysis in Japan.

Oncology

KW-0761 (product name in Japan, U.S. and Europe: POTELIGEO)

- ◆ In October 2022, we obtained approval of its indication for treatment of mycosis fungoides and Sézary syndrome in China.

KRN125 (product name in Japan: G-Lasta)

- In February 2022, we obtained approval of its indication for treatment of the mobilization of hematopoietic stem cells into peripheral blood for allogenic blood stem cell transplantation in Japan.
- In July 2022, we obtained approval for an automated injection device for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy in Japan.
- ◆ In December 2022, we launched “G-Lasta Subcutaneous Injection 3.6 mg BodyPod,” an automated injection device for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy, in Japan.

ME-401 (generic name: Zandelisib)

- ◆ Although global clinical studies had been conducted with MEI Pharma, Inc., global development of zandelisib outside of Japan for B-cell malignancies was discontinued in December 2022 after receiving the most recent guidance from the U.S. Food and Drug Administration (FDA).

Immunology and allergy

KHK4827 (product name in Japan: LUMICEF)

- In September 2022, we filed an application in Japan for a partial change for approval of its planned indication for palmoplantar pustulosis.

KHK4083/AMG 451 (generic name: rocatinlimab)

- ◆ In December 2022, enrollment for the multi-regional phase III clinical trial for atopic dermatitis was restarted.

Other

AMG531 (product name in Japan: Romiplate)

- In January 2022, we obtained approval of its indication for treatment of adult patients with chronic Immune Thrombocytopenia (ITP) who do not respond well to other treatments, such as corticosteroids and immunoglobulin, in China.

◆ In November 2022, we filed an application in Japan for a partial change for approval of its indication for treatment of aplastic anemia.

KRN23 (product name in Japan, U.S. and Europe: Crysvita)

- In August 2022, we obtained approval of its indication for treatment of tumor induced osteomalacia in Europe.

R&D pipeline

antibody　protein　small molecule　◎ New Molecular Entity　Updated since Dec. 31, 2021　Updated since Sep. 30, 2022

Nephrology　As of December 31, 2022

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Area	Stage: Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	Filed	Approved	[In-House or Licensed] Remarks
KHK7580 Evocalcet Oral	Calcimimetic	Secondary Hyperparathyroidism	CN TW						[Mitsubishi Tanabe Pharma] product name in Japan: Orkedia
			KR						
◎RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	Alport Syndrome	JP						[Reata]
		Diabetic Kidney Disease	JP						
		Autosomal Dominant Polycystic Kidney Disease	JP						
KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Preeclampsia	JP						[In-House] product name in Japan:Acoalan
KHK7791 Tenapanor Hydrochloride Oral	NHE3 Inhibitor	Hyperphosphatemia in Patients on Dialysis	JP						[Ardelyx]

Oncology

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Area	Stage: Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	Filed	Approved	[In-House or Licensed] Remarks
KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	CA KR AE						[In-House] POTELLIGENT® product name in Japan, U.S. and Europe: Poteligeo
			CN						
			IL						
			RS						
			KW						
KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony-Stimulating Factor	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogeneic Blood Stem Cell Transplantation	JP						[Amgen K-A] product name in Japan:G-Lasta
		Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	JP						
		Automated Injection Device for Decreasing the Incidence of Febrile Neutropenia in Patients Receiving Cancer Chemotherapy	JP						
◎ME-401 Zandelisib Oral	PI3Kδ Inhibitor	Indolent B-cell Non-Hodgkin's Lymphoma	JP						[MEI Pharma] Third line +

Immunology/Allergy

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Area	Stage: Ph I	Ph II	Ph III	Filed	Approved	[In-House or Licensed] Remarks
KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Ankylosing Spondylitis	TW MY					➡	[Amgen K-A] product name in Japan: Lumicef
		Ankylosing Spondylitis	TH				➡		
		Non-radiographic Axial Spondyloarthritis	TH				➡		
		Systemic Sclerosis	JP				➡		
		Palmoplantar Pustulosis	JP				➡		
©KHK4083/AMG 451 Rocatinlimab Injection	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	JP NA Europe			➡			[In-House] POTELLIGENT® Human Antibody-Producing Technology Collaboration agreement with Amgen for the development of KHK4083/AMG 451 in all the countries except for Japan.
©KK4277 Injection		Autoimmune Disease	JP	➡					[SBI Biotech]

Central Nervous System

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Area	Stage: Ph I	Ph II	Ph III	Filed	Approved	[In-House or Licensed] Remarks
©KHK6640 Injection	Anti–Amyloid Beta Peptide Antibody	Alzheimer's Disease	JP Europe	➡					[Immunas Pharma]

Other

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Area	Stage: Ph I	Ph II	Ph III	Filed	Approved	[In-House or Licensed] Remarks
KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	TH					➡	[In-House] Human Antibody-Producing Technology Jointly Developed with Ultragenyxin US and EU product name in Japan, U.S. and Europe: Crysvita
			MY					➡	
		Tumor Induced Osteomalacia (TIO)	Europe					➡	
AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Treatment of Adult Patients with Chronic Immune Thrombocytopenia (ITP) Who Do Not Respond Well to Other Treatments, Such as Corticosteroids and Immunoglobulin	CN					➡	[Amgen K-A] product name in Japan: Romiplate
		Treatment of Aplastic Anemia (AA) Which Is Refractory to Immunosuppressive Therapy or AA not Amenable to Immunosuppressive Therapy	SG					➡	
			TH MY					➡	
		Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	JP				➡		
			Asia			➡	Ph II / Ph III		
KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Europe	➡					[In-House] product name in Japan: Acoalan
KHK4951 Tivozanib Ophthalmic		Neovascular (wet) Age-Related Macular Degeneration	JP	➡					[In-House]

(5) Outlook for Fiscal 2023

(Billions of yen)

	Fiscal year ended December 31, 2022	**Outlook for fiscal 2023**	Year-on-year change	Rate of change (%)
Revenue	398.4	**426.0**	27.6	6.9%
Core operating profit	86.7	**88.0**	1.3	1.5%
Profit before tax	67.6	**94.0**	26.4	39.1%
Profit attributable to owners of parent	53.6	**76.0**	22.4	41.9%

Note: These forecasts assume average exchange rates of ¥130/US$, ¥160/British pound and ¥135/Euro.

Financial performance indicators

	Fiscal year ended December 31, 2022	**Outlook for fiscal 2023**	
ROE	7.1%	**9.7%**	Profit / Average beginning and ending equity
Revenue growth ratio (CAGR)	11.9%	**10.2%**	Annual average growth rate with fiscal 2020 as base year
R&D expense ratio	15.8%	**18.5%**	Research and development expenses / Revenue
Core operating profit ratio	21.8%	**20.7%**	Core operating profit / Revenue
Dividend payout ratio (Note)	38.9%	**39.9%**	

Note: The figure indicates the dividend payout ratio based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting “other income,” “other expenses” and the related “income tax expense” from “profit”) by the average number of shares during the period).

- Consolidated financial earnings forecasts for fiscal 2023 are for revenue of ¥426.0 billion (up 6.9% compared to the current fiscal year), core operating profit of ¥88.0 billion (up 1.5%), profit before tax of ¥94.0 billion (up 39.1%), and profit attributable to owners of parent of ¥76.0 billion (up 41.9%).
- Although we expect impacts such as a reduction in drug price standards scheduled for April 2023 in Japan, revenues are expected to increase compared to the current fiscal year due to growth in the global strategic products mainly Crysvita and an increase in licensing revenue. Although we expect increases in personnel expenses and sales promotion expenses to perform our own marketing for Crysvita in North America, and increases in expenses for investment in an IT/digital platform and human resources aimed at establishing competitive global business bases, we expect selling, general and administrative expenses to decrease as we will no longer be recording the profit share of costs for Crysvita after our own marketing begins from April. On the other hand, we are planning for significant increases in research and development expenses as a result of progress in development projects for products such as KHK4083 and KHK4951. However, we expect the increased gross profit resulting from expanded revenue will lead to higher core operating profit.
- A significant year-on-year increase is forecasted for profit before tax as a result of increased core operating profit, and a decline in other costs due to the recording of a significant amount of impairment losses in the current fiscal year.
- A year-on-year increase is forecasted for profit attributable to owners of parent despite an expected increase in income tax expense.
- Cash flows from operating activities are expected to result in a level of cash provided on par with the current fiscal year due to the recording of a large amount of impairment losses, which is a non-cash

item in profit before tax in the current fiscal year, despite profit before tax being expected to increase year on year.

- Concerning cash flows from investing activities, the Company expects a level of cash used on par with current fiscal year mainly because of proceeds from sale of investments in subsidiaries resulting from the cooperation for operating the established medicines business in Europe as a joint venture, despite an expected increase in cash used in the purchase of property, plant and equipment and intangible assets. Regarding strategic partnering, M&A and other strategic investments for acquiring R&D pipelines and drug discovery technologies, the Company will evaluate and conduct investment using a flexible approach.
- Concerning cash flows from financing activities, the Company expects net cash used to be at the same level as the current fiscal year. As regards the purchase of treasury shares and the sourcing of funds, we will remain flexible and act as appropriate for the economic and funding environment.

As a result of the above, cash and cash equivalents as of the end of fiscal 2023 are expected to be at the same level as at the end of fiscal 2022.

Note: The above financial position outlook is based on information available to management at the current time. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons.

(6) Basic Policy on Profit Distribution: Fiscal 2022 and Fiscal 2023 Dividends

The Company regards the return of profits to its shareholders as one of its key management priorities. The basis of the Company's policy regarding the distribution of profits is to pay dividends stably in light of a comprehensive consideration of factors including consolidated results and dividend payout ratio for each fiscal year, while also increasing its retained earnings for future business development and other purposes. We plan to improve our capital efficiency with regards to the purchase of treasury shares by taking a flexible approach while considering the share price in the market and other factors. The Company considers it a top priority to use internal reserve funds for investments for future growth (R&D investments, strategic investments and capital expenditures) in order to achieve sustainable growth from fiscal 2025 and maximize corporate value.
As the dividend policy, the Company set its target dividend payout ratio based on core EPS at 40% in the FY2021-2025 Medium Term Business Plan. The Company aims to ensure a stable and sustained increase in the level of dividend payment (continuous increase of dividend payments) in line with medium- to long-term growth in profits.
In accordance with the above-mentioned policy, the Board of Directors has resolved to pay a year-end dividend for fiscal 2022 of ¥27 per share. As a result, we expect to increase dividends for the sixth year in a row. The annual dividend is expected to be ¥51, an increase of ¥5 compared to the previous fiscal year, including an interim dividend of ¥24. With respect to the year-end dividend, we plan to submit a proposal at the 100th Ordinary General Meeting of Shareholders to be held on March 24, 2023.

Dividends of Surplus

	Details of resolution (March 24, 2023)	Dividend forecast most recently announced (Announced on February 7, 2022)	Fiscal 2021 results (Fiscal year ended December 31, 2021)
Record date	December 31, 2022	Same as left	December 31, 2021
Dividend per share (Yen)	27.00	24.00	23.00
Total dividend amount (Millions of yen)	14,512	–	12,359
Effective date	March 27, 2023	–	March 28, 2022
Dividend resource	Retained earnings	–	Retained earnings

(Reference) Breakdown of Dividends per Share

(Yen)

	Fiscal 2022 (Fiscal year ended December 31, 2022)	Dividend forecast most recently announced (Announced on February 7, 2022)	Fiscal 2021 results (Fiscal year ended December 31, 2021)
[Second quarter-end]	[24.00]	[24.00]	[23.00]
Fiscal year-end	27.00 (Note)	24.00	23.00
Dividends per share	51.00	48.00	46.00

Note: The fiscal year-end dividend (¥27.00) for the current term (fiscal year ended December 31, 2022) is based on the assumption that it will be approved at the 100th Ordinary General Meeting of Shareholders scheduled to be held on March 24, 2023.

For the fiscal year ending December 31, 2023, we expect to pay an annual dividend of ¥54 per share, an increase of ¥3 compared to the current fiscal year, consisting of an interim dividend of ¥27 and a year-end dividend of ¥27. For details of the "core EPS," refer to "(5) Outlook for Fiscal 2023."

2. Basic Rationale for Selection of Accounting Standards

The Group has applied IFRS from fiscal 2017 to enhance the international comparability of its financial information in the capital markets, and unify the process of the Group’s accounting.

3. Consolidated Financial Statements and Significant Notes Thereto

(1) Consolidated Statement of Financial Position

(Millions of yen)

	As of December 31, 2021	As of December 31, 2022
Assets		
Non-current assets		
Property, plant and equipment	78,652	89,099
Goodwill	136,352	135,761
Intangible assets	76,066	64,786
Other financial assets	45,164	36,531
Retirement benefit asset	15,298	15,212
Deferred tax assets	49,108	52,946
Other non-current assets	3,000	3,357
Total non-current assets	403,641	397,692
Current assets		
Inventories	64,089	70,675
Trade and other receivables	104,275	111,746
Other financial assets	1,434	526
Other current assets	13,350	14,094
Cash and cash equivalents	335,084	339,194
Subtotal	518,231	536,235
Assets held for sale	–	5,955
Total current assets	518,231	542,189
Total assets	921,872	939,881

(1) Consolidated Statement of Financial Position (continued)

(Millions of yen)

	As of December 31, 2021	As of December 31, 2022
Equity		
Share capital	26,745	26,745
Capital surplus	464,153	464,434
Treasury shares	(3,359)	(3,177)
Retained earnings	255,528	285,842
Other components of equity	(5,904)	(11,018)
Total equity attributable to owners of parent	737,162	762,826
Total equity	737,162	762,826
Liabilities		
Non-current liabilities		
Liabilities from application of equity method	19,426	15,529
Retirement benefit liability	221	287
Provisions	7,757	7,532
Deferred tax liabilities	386	404
Other financial liabilities	16,594	17,549
Other non-current liabilities	31,197	25,929
Total non-current liabilities	75,581	67,229
Current liabilities		
Trade and other payables	64,652	70,922
Provisions	1,580	2,966
Other financial liabilities	5,943	5,729
Income taxes payable	13,426	1,582
Other current liabilities	23,528	28,627
Total current liabilities	109,129	109,825
Total liabilities	184,710	177,055
Total equity and liabilities	921,872	939,881

(2) Consolidated Statement of Profit or Loss and Consolidated Statement of Comprehensive Income

Consolidated Statement of Profit or Loss

(Millions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Revenue	352,246	398,371
Cost of sales	(87,849)	(86,915)
Gross profit	264,398	311,455
Selling, general and administrative expenses	(145,608)	(166,185)
Research and development expenses	(57,679)	(62,896)
Share of profit (loss) of investments accounted for using equity method	4,575	4,323
Other income	985	1,705
Other expenses	(6,616)	(23,061)
Finance income	1,113	3,319
Finance costs	(1,117)	(1,088)
Profit before tax	60,050	67,572
Income tax expense	(7,703)	(14,000)
Profit	52,347	53,573
Profit attributable to		
Owners of parent	52,347	53,573
Earnings per share		
Basic earnings per share (Yen)	97.43	99.68
Diluted earnings per share (Yen)	97.39	99.66

Consolidated Statement of Comprehensive Income

(Millions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Profit	52,347	53,573
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(1,623)	1,068
Remeasurements of defined benefit plans	1,411	961
Total of items that will not be reclassified to profit or loss	(212)	2,029
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	10,498	(5,068)
Share of other comprehensive income of investments accounted for using equity method	118	121
Total of items that may be reclassified to profit or loss	10,616	(4,948)
Other comprehensive income	10,404	(2,918)
Comprehensive income	62,751	50,654
Comprehensive income attributable to		
Owners of parent	62,751	50,654

(3) Consolidated Statement of Changes in Equity

Fiscal year ended December 31, 2021

(Millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Share acquisition rights	Exchange differences on translation of foreign operations
Balance at January 1, 2021	26,745	463,967	(3,545)	226,639	596	(17,915)
Profit	–	–	–	52,347	–	–
Other comprehensive income	–	–	–	–	–	10,616
Total comprehensive income	–	–	–	52,347	–	10,616
Dividends of surplus	–	–	–	(24,176)	–	–
Purchase of treasury shares	–	–	(23)	–	–	–
Disposal of treasury shares	–	61	121	–	–	–
Share-based remuneration transactions	–	126	88	–	(181)	–
Transfer from other components of equity to retained earnings	–	–	–	717	–	–
Total transactions with owners	–	187	186	(23,459)	(181)	–
Balance at December 31, 2021	26,745	464,153	(3,359)	255,528	414	(7,299)

	Equity attributable to owners of parent				Total equity
	Other components of equity			Total	
	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
Balance at January 1, 2021	1,909	–	(15,410)	698,396	698,396
Profit	–	–	–	52,347	52,347
Other comprehensive income	(1,623)	1,411	10,404	10,404	10,404
Total comprehensive income	(1,623)	1,411	10,404	62,751	62,751
Dividends of surplus	–	–	–	(24,176)	(24,176)
Purchase of treasury shares	–	–	–	(23)	(23)
Disposal of treasury shares	–	–	–	182	182
Share-based remuneration transactions	–	–	(181)	32	32
Transfer from other components of equity to retained earnings	694	(1,411)	(717)	–	–
Total transactions with owners	694	(1,411)	(898)	(23,985)	(23,985)
Balance at December 31, 2021	980	–	(5,904)	737,162	737,162

(3) Consolidated Statement of Changes in Equity (continued)

Fiscal year ended December 31, 2022

(Millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Share acquisition rights	Exchange differences on translation of foreign operations
Balance at January 1, 2022	26,745	464,153	(3,359)	255,528	414	(7,299)
Profit	–	–	–	53,573	–	–
Other comprehensive income	–	–	–	–	–	(4,948)
Total comprehensive income	–	–	–	53,573	–	(4,948)
Dividends of surplus	–	–	–	(25,258)	–	–
Purchase of treasury shares	–	–	(11)	–	–	–
Disposal of treasury shares	–	(35)	118	–	–	–
Share-based remuneration transactions	–	315	76	–	(196)	–
Transfer from other components of equity to retained earnings	–	–	–	2,000	–	–
Total transactions with owners	–	281	183	(23,258)	(196)	–
Balance at December 31, 2022	26,745	464,434	(3,177)	285,842	219	(12,247)

	Equity attributable to owners of parent				Total equity
	Other components of equity			Total	
	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
Balance at January 1, 2022	980	–	(5,904)	737,162	737,162
Profit	–	–	–	53,573	53,573
Other comprehensive income	1,068	961	(2,918)	(2,918)	(2,918)
Total comprehensive income	1,068	961	(2,918)	50,654	50,654
Dividends of surplus	–	–	–	(25,258)	(25,258)
Purchase of treasury shares	–	–	–	(11)	(11)
Disposal of treasury shares	–	–	–	83	83
Share-based remuneration transactions	–	–	(196)	195	195
Transfer from other components of equity to retained earnings	(1,038)	(961)	(2,000)	–	–
Total transactions with owners	(1,038)	(961)	(2,195)	(24,990)	(24,990)
Balance at December 31, 2022	1,010	–	(11,018)	762,826	762,826

(4) Consolidated Statement of Cash Flows

(Millions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Cash flows from operating activities		
Profit before tax	60,050	67,572
Depreciation and amortization	19,498	18,476
Impairment losses	5,286	17,979
Increase (decrease) in provisions	(608)	1,570
Share of loss (profit) of investments accounted for using equity method	(4,575)	(4,323)
Decrease (increase) in inventories	(8,280)	(8,896)
Decrease (increase) in trade receivables	(5,901)	(2,704)
Increase (decrease) in trade payables	(126)	(5,867)
Increase (decrease) in contract liabilities	38,767	(7,321)
Income taxes paid	(14,838)	(22,559)
Other	(2,727)	(5,255)
Net cash provided by (used in) operating activities	86,548	48,672
Cash flows from investing activities		
Purchase of property, plant and equipment	(6,522)	(15,564)
Purchase of intangible assets	(13,244)	(13,102)
Proceeds from sale of investments accounted for using equity method	5,097	–
Purchase of investment securities	(315)	(1,908)
Proceeds from sale of investment securities	1,914	3,687
Advance receipt from sale of investment securities	–	4,229
Proceeds from redemption of bonds of subsidiaries and associates	1,500	4,000
Other	208	1,473
Net cash provided by (used in) investing activities	(11,363)	(17,185)
Cash flows from financing activities		
Repayments of lease liabilities	(3,475)	(3,767)
Purchase of treasury shares	(23)	(11)
Dividends paid	(24,176)	(25,258)
Other	(771)	3
Net cash provided by (used in) financing activities	(28,446)	(29,032)
Effect of exchange rate changes on cash and cash equivalents	1,325	1,655
Net increase (decrease) in cash and cash equivalents	48,065	4,111
Cash and cash equivalents at beginning of period (Amount on the consolidated statement of financial position)	287,019	335,084
Cash and cash equivalents at beginning of period	287,019	335,084
Cash and cash equivalents at end of period	335,084	339,194

(5) Notes to Consolidated Financial Statements

Notes on going concern assumption

No applicable items.

Changes in presentation

Consolidated Statement of Cash Flows

"Purchase of investment securities" and "Proceeds from redemption of bonds of subsidiaries and associates," which had previously been included in "Other" of "Cash flows from investing activities" in the fiscal year ended December 31, 2021, has been presented separately because its monetary importance has increased. To reflect this change in the presentation method, we have reclassified the amount in our Consolidated Financial Statements for the fiscal year ended December 31, 2021.

As a result, in the Consolidated Statement of Cash Flows for the fiscal year ended December 31, 2021, ¥1,393 million presented as "Other" in "Cash flows from investing activities" was reclassified as "Purchase of investment securities" of negative ¥315 million, "Proceeds from redemption of bonds of subsidiaries and associates" of ¥1,500 million and "Other" of ¥208 million.

Segment information, etc.

(1) Outline of reportable segments

The Group omitted information by reportable segment as the Group consists of only the one reportable segment, which is the Pharmaceuticals business.

(2) Information about products and services

Breakdown of revenue from external customers by product and service is as follows.

(Millions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Products	326,141	364,596
Licensing revenue	26,105	33,775
Total	352,246	398,371

(3) Information about geographical areas

i. Revenue

(Millions of yen)

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Japan	161,988	154,636
Americas	102,163	143,905
(Of which, the U.S.)	99,328	139,852
Europe	53,361	62,251
Asia	34,518	37,368
Other	217	210
Total	352,246	398,371

Note: Revenue is classified by region or country based on location of customer.

ii. Non-current assets

(Millions of yen)

	As of December 31, 2021	As of December 31, 2022
Japan	227,854	226,529
Americas	11,526	13,508
Europe	51,669	49,253
Asia	3,021	3,713
Total	294,070	293,002

Note: Non-current assets are classified based on the location of assets, and do not include investments accounted for using the equity method, financial instruments, retirement benefit asset and deferred tax assets.

(4) Information about major customers

The customer that accounts for 10% or more of revenue in the consolidated statement of profit or loss is as follows:

(Millions of yen)

Customer	Fiscal year ended December 31, 2021	Fiscal year ended December 31,2022
Alfresa Corporation	35,457	–

Note: Revenue of Alfresa Corporation in the fiscal year ended December 31,2022 is not presented because it is less than 10% of revenue stated in the consolidated statement of profit or loss.

Per share information

	Fiscal year ended December 31, 2021	Fiscal year ended December 31, 2022
Profit attributable to ordinary equity holders of parent		
Profit attributable to owners of parent *(Millions of yen)*	52,347	53,573
Profit not attributable to ordinary equity holders of parent *(Millions of yen)*	–	–
Profit used to calculate earnings per share *(Millions of yen)*	52,347	53,573
Weighted average number of ordinary shares outstanding during year *(Shares)*	537,272,070	537,431,734
Increase in number of ordinary shares		
Share acquisition rights *(Shares)*	242,100	138,523
Weighted average number of dilutive potential ordinary shares during year *(Shares)*	537,514,170	537,570,257
Earnings per share		
Basic earnings per share *(Yen)*	97.43	99.68
Diluted earnings per share *(Yen)*	97.39	99.66

Significant subsequent events

No applicable items.