Kyowa Kirin Co., Ltd.

Consolidated Financial Summary (IFRS)
Fiscal 2024 Semi Annual

(January 1, 2024 – June 30, 2024)

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

SUMMARY OF CONSOLIDATED FINANCIAL STATEMENTS (IFRS)
for Six Months Ended June 30, 2024

August 1, 2024

Company Name: Kyowa Kirin Co., Ltd.
Listed Exchanges: Tokyo Stock Exchange
Stock Code: 4151
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Inquiries: Hiroki Nakamura
Executive Vice President,
Corporate Communications Department
URL: https://www.kyowakirin.com/index.html
Scheduled date of submission of Semi-Annual Securities Report: August 1, 2024
Scheduled start date of dividend payment: September 2, 2024
Appendix materials to accompany the financial report: Yes
Results presentation meeting: Yes (for institutional investors and securities analysts)

(Millions of yen rounded off)

1. Consolidated Financial Results for the Six Months Ended June 30, 2024

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

	Revenue		Core operating profit		Profit before tax		Profit	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
June 30, 2024	232,974	16.9	44,136	17.8	46,522	78.6	37,777	74.5
June 30, 2023	199,209	7.5	37,467	(6.1)	26,046	(40.1)	21,646	(38.2)

Total comprehensive income: Six months ended June 30, 2024: ¥68,998 million; 49.5%
Six months ended June 30, 2023: ¥46,154 million; 13.8%

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
Six months ended	Millions of yen	%	Yen	Yen
June 30, 2024	37,777	74.5	70.76	70.75
June 30, 2023	21,646	(38.2)	40.27	40.26

(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
As of	Millions of yen	Millions of yen	Millions of yen	%
June 30, 2024	1,070,009	862,688	862,688	80.6
December 31, 2023	1,025,942	836,418	836,418	81.5

2. Dividends

	Dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2023	–	27.00	–	29.00	56.00
Fiscal year ending December 31, 2024	–	29.00			
Fiscal year ending December 31, 2024 (Forecast)			–	29.00	58.00

Note: Revisions to the dividend forecast most recently announced: None

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2024 (from January 1, 2024 to December 31, 2024)

(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	492,000	11.3	92,000	(4.9)	92,000	(5.3)	68,000	(16.2)	68,000	(16.2)	128.42

Note: Changes to the earnings forecasts most recently announced: Yes

*** Notes**

(1) Significant changes in the scope of consolidation during the period under review: Yes

Newly included: one company Orchard Therapeutics plc

(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 June 30, 2024	540,000,000 shares
As of December 31, 2023	540,000,000 shares

b. Number of treasury shares

As of June 30, 2024	12,275,511 shares
As of December 31, 2023	2,390,712 shares

c. Average number of shares during the period

Six months ended June 30, 2024	533,877,966 shares
Six months ended June 30, 2023	537,546,084 shares

* Semi-annual financial results reports are exempt from review 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.

Attachment Index

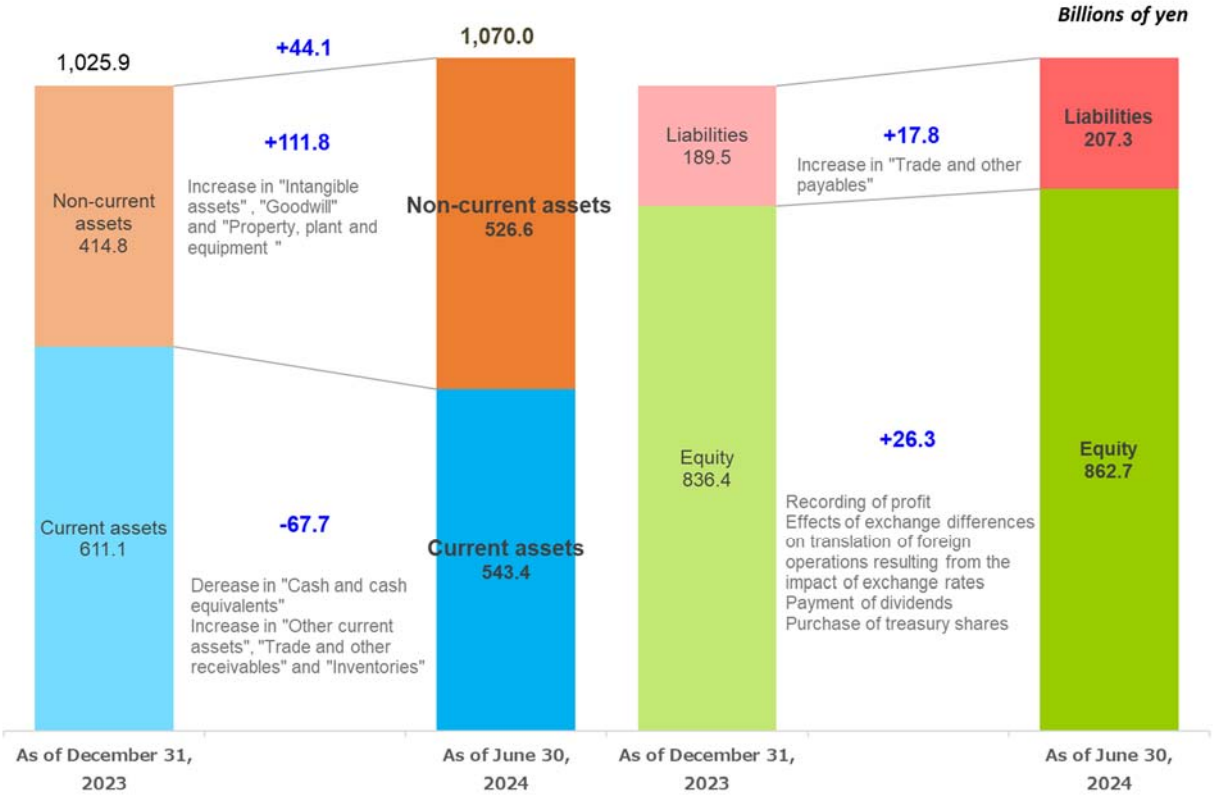
1. Operating Results and Financial Statements

(1) Summary of Consolidated Financial Position

(Billions of yen)

	As of December 31, 2023	As of June 30, 2024	Year-on-year change
Assets	1,025.9	1,070.0	44.1
Non-current assets	414.8	526.6	111.8
Current assets	611.1	543.4	(67.7)
Liabilities	189.5	207.3	17.8
Equity	836.4	862.7	26.3
Ratio of equity attributable to owners of parent to total assets (%)	81.5%	80.6%	(0.9)%

- Assets as of June 30, 2024, were ¥1,070.0 billion, an increase of ¥44.1 billion compared to the end of the previous fiscal year.
  - Non-current assets increased by ¥111.8 billion compared to the end of the previous fiscal year, to ¥526.6 billion, due mainly to an increase in goodwill and intangible assets as a result of the business combination associated with the acquisition of shares of Orchard Therapeutics plc, in addition to the purchase of intangible assets through the introduction of development products and the purchase of property, plant and equipment.
  - Current assets decreased by ¥67.7 billion compared to the end of the previous fiscal year, to ¥543.4 billion, due mainly to a decrease in cash and cash equivalents, despite an increase in other current assets such as deposits for the purchase of treasury shares as well as increases in trade and other receivables and inventories.
- Liabilities as of June 30, 2024, were ¥207.3 billion, an increase of ¥17.8 billion compared to the end of the previous fiscal year, due mainly to an increase in trade and other payables.
- Equity as of June 30, 2024, was ¥862.7 billion, an increase of ¥26.3 billion compared to the end of the previous fiscal year, due mainly to an increase due to the recording of profit attributable to owners of parent as well as an increase in exchange differences on translation of foreign operations resulting from the impact of exchange rates, despite a decrease due to the payment of dividends, in addition to the purchase of treasury shares. As a result, the ratio of equity attributable to owners of parent to total assets as of June 30, 2024 was 80.6%, a decrease of 0.9 percentage points compared to the end of the previous fiscal year.


Billions of yen
1,025.9
+44.1
1,070.0
Non-current assets 414.8
+111.8
Increase in "Intangible assets", "Goodwill" and "Property, plant and equipment "
Non-current assets 526.6
Current assets 611.1
-67.7
Derease in "Cash and cash equivalents"
Increase in "Other current assets", "Trade and other receivables" and "Inventories"
Current assets 543.4
As of December 31, 2023
As of June 30, 2024
Liabilities 189.5
+17.8
Increase in "Trade and other payables"
Liabilities 207.3
Equity 836.4
+26.3
Recording of profit
Effects of exchange differences on translation of foreign operations resulting from the impact of exchange rates
Payment of dividends
Purchase of treasury shares
Equity 862.7
As of December 31, 2023
As of June 30, 2024

(2) Summary of Consolidated Business Performance

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)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change	Rate of change (%)
Revenue	199.2	233.0	33.8	16.9%
Core operating profit	37.5	44.1	6.7	17.8%
Profit before tax	26.0	46.5	20.5	78.6%
Profit attributable to owners of parent	21.6	37.8	16.1	74.5%

< Average exchange rates for each period >

Currency	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change
USD (USD/¥)	¥134	¥151	Up ¥17
GBP (GBP/¥)	¥164	¥191	Up ¥27
EUR (EUR/¥)	¥144	¥163	Up ¥19

For the six months ended June 30, 2024 (January 1, 2024 to June 30, 2024), revenue was ¥233.0 billion (up 16.9% compared to the same period of the previous fiscal year), and core operating profit was ¥44.1 billion (up 17.8%). Profit attributable to owners of parent was ¥37.8 billion (up 74.5%).

- The increase in revenue was the result of growth of global strategic products mainly in North America and a rise in revenue from technology out-licensing. The positive effect on revenue from foreign exchange was ¥18.6 billion.
- Core operating profit increased as a result of higher gross profit achieved due to gains in overseas revenue and revenue from technology out-licensing, despite significantly higher research and development expenses. The positive effect on core operating profit from foreign exchange was ¥6.3 billion.
- Profit attributable to owners of parent increased as a result of a decrease in other expenses due mainly to a decrease in impairment losses, and as a result of an increase in other income due mainly to a gain on sale of non-current assets.

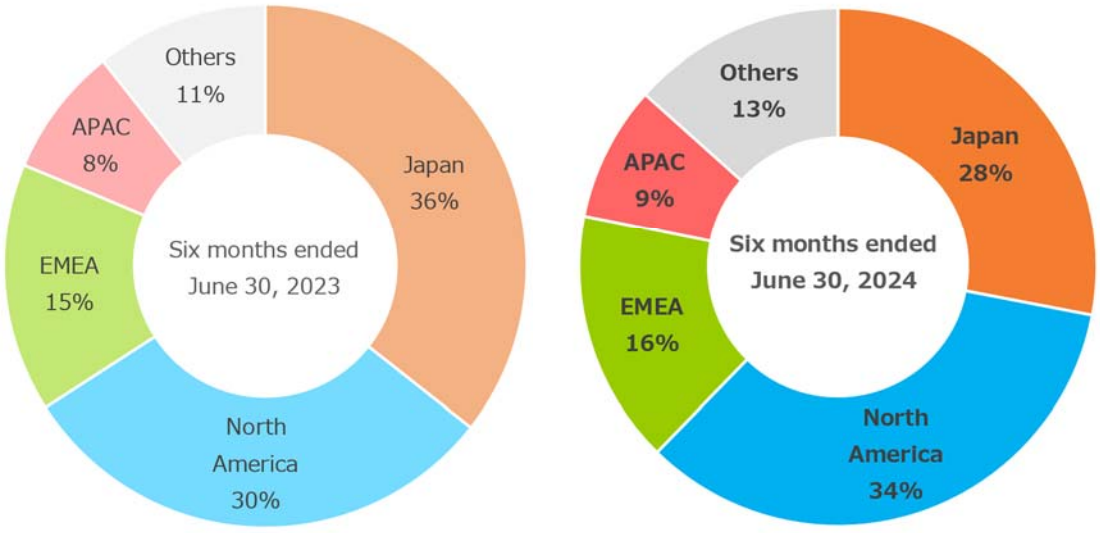
2) Revenue by regional control function

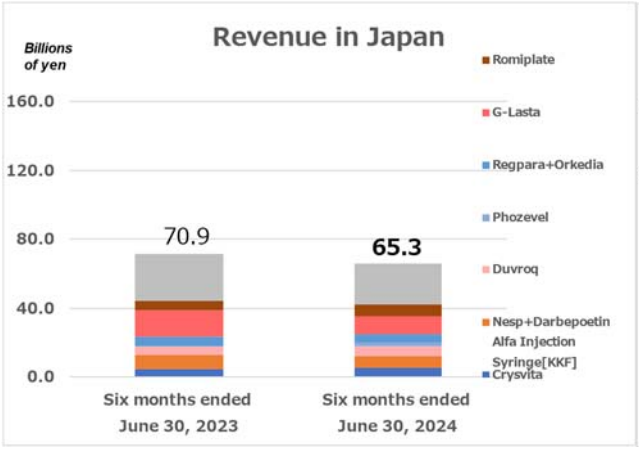
(Billions of yen)

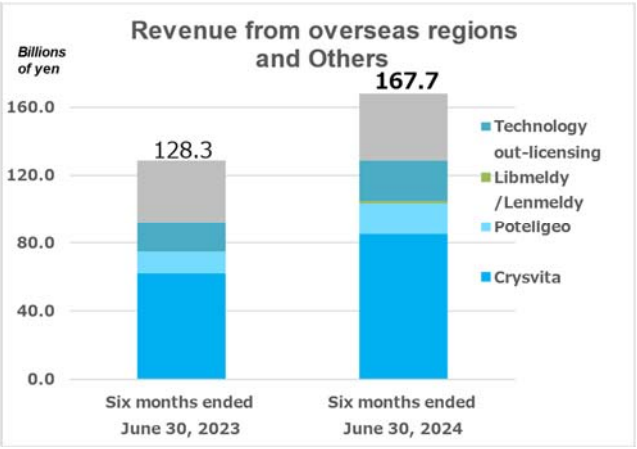
	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change	Rate of change (%)
Japan	70.9	65.3	(5.7)	(8.0)%
North America	60.3	79.9	19.6	32.5%
EMEA	30.8	36.9	6.1	19.9%
APAC	16.0	19.8	3.8	23.7%
Others	21.2	31.1	9.9	46.8%
Total consolidated revenue	199.2	233.0	33.8	16.9%

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, hematopoietic stem cell gene therapy (revenue from Orchard Therapeutics plc), original equipment manufacturing, etc.

Composition of revenue by regional control function







< Revenue in Japan region >

(Billions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change	Rate of change (%)
Crysvita	4.8	5.4	0.5	11.1%
Darbepoetin Alfa Injection Syringe [KKF]	6.9	5.6	(1.3)	(18.6)%
Duvroq	4.2	5.7	1.4	33.8%
PHOZEVEL	–	1.7	1.7	–
G-Lasta	15.0	10.5	(4.5)	(30.1)%

- Revenue in Japan decreased year on year due mainly to the impact of the reductions in drug price standards implemented in April 2023 and April 2024, despite the growth in sales of Duvroq, a treatment for renal anemia, and the launch of PHOZEVEL, a treatment for hyperphosphatemia.
  - Revenue from Crysvita, a treatment for FGF23-related diseases, has been growing steadily since its launch in 2019.
  - Revenue from Darbepoetin Alfa Injection Syringe [KKF], a treatment for renal anemia, 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 steadily since its launch in 2020.
  - Revenue from PHOZEVEL, a treatment for hyperphosphatemia launched on February 20, 2024, has been growing steadily as a result of penetrating the market.
  - Revenue from G-Lasta, an agent for decreasing the incidence of febrile neutropenia, decreased due to the impact of biosimilar products launched in November 2023.

<Revenue from overseas regions and Others>

(Billions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change	Rate of change (%)
Crysvita	61.9	85.5	23.6	38.1%
Poteligeo	12.5	18.1	5.7	45.5%
Libmeldy/Lenmeldy	–	1.4	1.4	–

- 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 steadily since its launch in 2018.
  - Revenue from Poteligeo, an anticancer agent, has been growing since its launch in 2018.

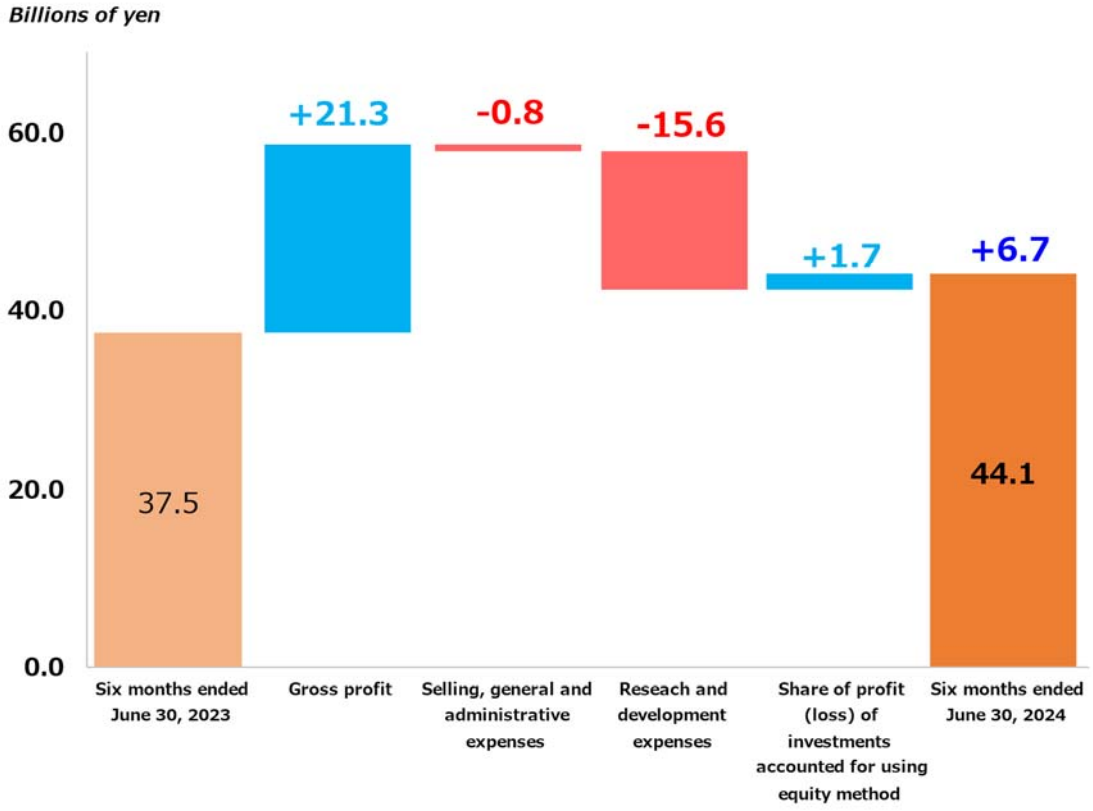
- Revenue in EMEA increased year on year due to the growth of global strategic products, despite a drop in revenue from the established medicines.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing since its launch in 2018, as the number of countries where it has been released and its indications have expanded.
  - 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 2020.
  - Following the shift to a joint venture with Grünenthal GmbH for the established medicines business, in August 2023, revenue for 13 brands shifted from product sales to sales royalties and license fees, which led to a decrease in revenue from established medicines such as Abstral.

- Revenue in APAC increased year on year.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily.

- Revenue from Others increased year on year.
  - As a result of the new consolidation of Orchard Therapeutics plc, revenue was recorded for Libmeldy (approval was obtained in the United States in March 2024 under the product name of Lenmeldy), which is sold by that company in Europe for treatment of metachromatic leukodystrophy (MLD).
  - Revenue increased due to an increase in royalties revenue from AstraZeneca in relation to benralizumab and the proceeds from an upfront payment from Boehringer Ingelheim.

3) Core operating profit

- Core operating profit increased year on year due to growth in revenue from global strategic products mainly in North America and a rise in gross profit from revenue from technology out-licensing, despite a significant increase in research and development expenses as a result of progress in development for KHK4083, for which a multiregional phase III clinical trial is ongoing, and the new consolidation of Orchard Therapeutics plc.

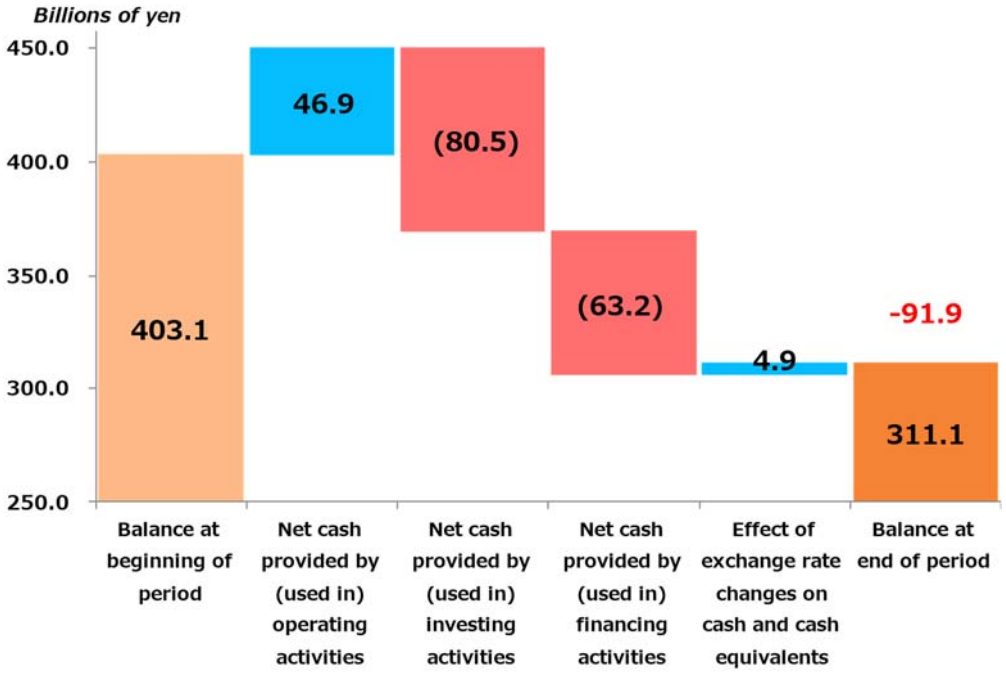


(3) Summary of Consolidated Cash Flows

(Billions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year change	Rate of change (%)
Net cash provided by (used in) operating activities	60.3	46.9	(13.5)	(22.4)%
Net cash provided by (used in) investing activities	(14.0)	(80.5)	(66.5)	476.8%
Net cash provided by (used in) financing activities	(16.1)	(63.2)	(47.2)	293.5%
Cash and cash equivalents at beginning of period	339.2	403.1	63.9	18.8%
Cash and cash equivalents at end of period	372.1	311.1	(61.0)	(16.4)%

- Cash and cash equivalents as of June 30, 2024 were ¥311.1 billion, a decrease of ¥91.9 billion compared with the balance of ¥403.1 billion as of December 31, 2023.
  The main contributing factors affecting cash flow during the six months ended June 30, 2024 were as follows:
- Net cash provided by operating activities was ¥46.9 billion, compared with net cash provided by operating activities of ¥60.3 billion in the same period of the previous fiscal year. Major inflows were depreciation and amortization of ¥12.1 billion and foreign exchange loss (gain) of ¥6.3 billion mainly relating to exchange differences on translation of foreign currency denominated deposits from consolidated subsidiaries as of June 30, 2024, in addition to profit before tax of ¥46.5 billion. Major outflows were decrease in contract liabilities of ¥5.8 billion and income taxes paid of ¥5.8 billion.
- Net cash used in investing activities was ¥80.5 billion, compared with net cash used in investing activities of ¥14.0 billion in the same period of the previous fiscal year. Major outflows were ¥48.2 billion for the acquisition of shares of Orchard Therapeutics plc, purchase of intangible assets of ¥21.9 billion, and purchase of property, plant and equipment of ¥13.1 billion. A major inflow was proceeds from sale of property, plant and equipment of ¥3.4 billion.
- Net cash used in financing activities was ¥63.2 billion, compared with net cash used in financing activities of ¥16.1 billion in the same period of the previous fiscal year. Major outflows were the purchase of treasury shares of ¥27.0 billion, dividends paid of ¥15.6 billion, redemption of bonds with share acquisition rights issued by Orchard Therapeutics plc of ¥9.6 billion, and an increase in deposits for the purchase of treasury shares of ¥9.0 billion.



(4) Research and Development Activities

The Group continuously and actively invests resources in research and development activities. The Group aims to continually create new drugs with life-changing value by including bone and mineral, intractable hematological diseases and hemato oncology, and rare disease in the disease science field in which it focuses its in-house research and development, and, with regard to drug discovery technology, strengthening innovative modalities such as advanced antibody technologies and hematopoietic stem cell gene therapy. The Group will also continue to promote open innovation activities, collaborate with partners, invest in venture capital funds, and engage in corporate venture capital activities. The Group choses an appropriate business model with life-changing value created, promotes the development of assets in focus disease areas with the aim of expanding them globally. At the same time, for assets outside of the disease areas of focus disease areas, the Group achieves value maximization through strategic collaboration with external partners. In addition, effective January 2024, the Research and Development Division was reorganized to create the Research Division and the Development Division. In addition to creating a research environment that creates innovation, we will build a system that enables development activities tailored to the potential of each development product.

For the six months ended June 30, 2024, the Group's research and development expenses totaled ¥49.2 billion.

<Development status of major development products>

As of June 30, 2024

Code, Generic Name	Indication	Development status
rocatinlimab	Moderate and severe atopic dermatitis	Ph III clinical study: in progress
	Moderate and severe asthma	Ph II clinical study: in progress
	Prurigo nodularis	Ph III clinical study: preparation underway
KHK4951, tivozanib	Neovascular Age-related Macular Degeneration (nAMD)	Ph II clinical study: in progress
	Diabetic Macular Edema (DME)	Ph II clinical study: in progress
KK4277	Erythematosus (SLE)/Cutaneous Lupus Erythematosus (CLE)	Ph I clinical study: in progress
KK2260	Solid tumors	Ph I clinical study: in progress
KK2269	Solid tumors	Ph I clinical study: in progress
KK2845	Acute Myeloid Leukemia (AML)	Ph I clinical study: preparation underway
KK8123	X-linked Hypophosphatemia (XLH)	Ph I clinical study: preparation underway
OTL-203	Mucopolysaccharidosis type IH (Hurler syndrome)	Pivotal study (Equivalent to Ph III study): in progress
OTL-201	Mucopolysaccharidosis type IIIA (Sanfilippo syndrome type A)	PoC study (Equivalent to Ph I/II study) : in progress

・ Rocatinlimab is a T cell rebalancing monoclonal antibody that inhibits and reduces pathogenic T cells by targeting the OX40 receptor. The initial antibody was discovered in collaboration between research team of Kyowa Kirin in United States and La Jolla Institute for Immunology. On June 1, 2021, Kyowa Kirin and Amgen entered into an agreement to jointly develop and commercialize rocatinlimab. Under the terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for rocatinlimab for all markets globally, except Japan, where Kyowa Kirin will retain all rights. If approved, the companies will co-promote the asset in the United States and Kyowa Kirin has opt-in rights to co-promote in certain other markets including Europe and Asia. Phase III clinical studies evaluating rocatinlimab in moderate to severe atopic dermatitis (ROCKET Program) is composed of eight studies enrolling adult and adolescent patients. To date, over 3,100 patients have been enrolled in the ROCKET Program with five

studies having completed enrollment. Moreover, a Phase II clinical study in moderate to severe asthma was started in May 2024. A Phase III clinical study in prurigo nodularis is also under preparation.

- Tivozanib, the active ingredient of KHK4951 is a small-molecule vascular endothelial growth factor receptor (VEGFR) -1, -2, and -3 tyrosine kinase inhibitor (TKI) discovered and developed by Kyowa Kirin. KHK4951 is a novel nano-crystalized tivozanib eye drops designed to deliver it efficiently to the posterior ocular tissues and has the potential to provide a novel non-invasive treatment option for patients with neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). Phase II clinical studies have been conducted.

- KK4277 is an optimized antibody based on antibodies licensed from SBI Biotech. It has been enhanced with antibody-dependent cell-mediated cytotoxicity (ADCC) activity using our POTELLIGENT technology. Phase I clinical study for the treatment of systemic lupus erythematosus and cutaneous lupus erythematosus has been conducted.

- KK2260 is an EGFR-TfR1 bispecific antibody developed using the Company's proprietary bispecific antibody technology REGULGENT. It is designed as an antibody that achieves selective iron depletion in cancer cells, and in non-clinical trials it showed high efficacy and tolerability. Phase I clinical trial is ongoing.

- KK2269 is an EpCAM-CD40 bispecific antibody developed using the Company's proprietary bispecific antibody technology REGULGENT. It is designed as an antibody that activates only antigen-presenting cells near the tumor by cross-linking EpCAM, which is highly expressed in various tumors, with CD40 on antigen-presenting cells. In non-clinical trials, it was found to exhibit the therapeutic effects of anti-tumor immunity while suppressing systemic side effects. Phase I clinical trial is ongoing.

- KK2845 is the Company's first development product of antibody-drug conjugate (ADC). The target molecule is TIM-3, and the Company is currently preparing for Phase I clinical trial targeting acute myeloid leukemia.

- KK8123 is a potential new treatment for X-linked Hypophosphatemia (XLH) patients which is a human antibody targeting FGF23 in preparation of Phase I study for XLH.

- OTL-203 is an investigational HSC gene therapy in development for the treatment of mucopolysaccharidosis type IH (Hurler syndrome). Orchard Therapeutics is currently implementing a pivotal study (equivalent to a Phase III clinical study) of OTL-203 as a therapy to potentially correct the underlying cause of Hurler syndrome.

- OTL-201 is an investigational HSC gene therapy in development for the treatment of mucopolysaccharidosis type IIIA (Sanfilippo syndrome). A proof-of-concept (Equivalent to Phase I / II study) is ongoing.

<Major collaboration and licensing information>

- In January 2024, Boehringer Ingelheim and Kyowa Kirin have entered into a license agreement. Under the terms of the agreement, Kyowa Kirin license out exclusive rights of a new compound to Boehringer Ingelheim to develop treatments for fibro-inflammatory diseases.
- In February 2024, a partnership wherein BridgeBio's affiliate, QED Therapeutics, grants Kyowa Kirin an exclusive license to develop and commercialize infigratinib for skeletal dysplasias in Japan, aiming successful portfolio in the therapeutic areas of bone and mineral diseases.

R&D pipeline

small molecule　large molecule　antibody　HSC-GT　Updated since Dec. 31, 2023　✓ Updated since Mar. 31, 2024

As of Jun. 30, 2024

Code Name Generic Name Formulation	Mechanizm of Action	Indication	Stage	[In-House or Licensed] Remarks
KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia	PhI	[In-House] Preparation underway for PhI as a global product
KK2845	Anti-TIM-3 ADC	Acute Myelogenous Leukemia	PhI	[In-House] Antibody-Drug Conjugate Preparation underway for PhI in Japan as a global product
OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)	PhI → PhII → PhIII	[In-House] Rare Pediatric Disease (RPD) and Fast Track designations (FDA) Priority Medicines (PRIME) designation (EMA) Area of clinical study: NA and EU
OTL-201	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IIIA (Sanfilippo Syndrome type A)	PhI → Ph I / Ph II	[In-House] Rare Pediatric Disease (RPD) designation (FDA) Preparation underway for registrational study (equivalent to Ph Ⅲ study)
KHK4083/AMG 451 rocatinlimab Injection	Anti-OX40 Antibody	Moderate to Severe Atopic Dermatitis	PhI → PhII → PhIII	[In-House] POTELLIGENT Human monoclonal antibody production technology Collaboration agreement with Amgen for the development of rocatinlimab in all the countries except for Japan. Clinical study is being conducted in JP, NA, EU, UK, Middle East, Asia, Oceania, and other regions as a global product
		Moderate to Severe Asthma	PhI → ✓	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
		Prurigo Nodularis	PhI	Preparation underway for Ph Ⅲ as a global product
KHK4951 tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Diabetic Macular Edema	PhI → PhII	[In-House] Clinical sudy is being conducted in JP, NA, Asia, and Oceania as a global product
		Neovascular Age-Related Macular Degeneration	PhI → PhII	Clinical sudy is being conducted in JP, NA, Asia, and Oceania as a global product
KK2260 Injection	EGFR-TfR1Bispecific Antibody	Solid Tumor	PhI	[In-House] REGULGENT Fully human antibody production technology A clinical sudy is being conducted in JP, and a clinical study is prepared under way for PH I in NA as a global product.
KK2269 Injection	EpCAM-CD40Bispecific Antibody	Solid Tumor	PhI	[In-House] REGULGENT Fully human antibody production technology Clinical sudy is being conducted in JP and NA as a global product
AMG531 romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Previously Untreated with Immunosuppressive Therapy	PhI → PhII → Ph Ⅱ / Ph Ⅲ	[Amgen K-A] product name in Japan: Romiplate Area of clinical study: Asia
KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus	PhI	[SBI Biotech] POTELLIGENT Clinical sudy is being conducted in JP and Asia

Major Applications and Approvals

Code Name, Generic Name, Product Name	Indication	Application/ Under Review	Countries/ Regions Received Approval in 2024
KRN125 (pegfilgrastim, Product name in Japan: G-LASTA)	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	—	JP
OTL-200 (atidarsagene autotemcel, Product name in Europe/US: Libmeldy/Lenmeldy)	Metachromatic Leukodystrophy	—	US
KHK4827 (brodalumab, Product name in Japan and Asia: Lumicef)	Systemic Sclerosis	JP	—
	Palmoplantar pustulosis	TW	—
KHK7580 (Evocalcet, Product name in Japan: Orkedia)	Secondary Hyperparathyroidism	—	TW/CN
AMG531 (Romiplostim, Product name in Japan: Romiplate)	Aplastic anemia	TW	—
	Severe aplastic anemia	KR	—

(5) Summary of Consolidated Earnings Forecasts and Other Forward-looking Statements

The consolidated earnings up to the end of the six months ended June 30, 2024 show steady progress that is exceeding initial expectations, partly due to the impact of exchange rates caused by significant depreciation of the yen. In addition, the assumed average foreign exchange rates have been adjusted from the previous ¥140/USD to ¥151/USD, ¥180/GBP to ¥191/GBP, and ¥155/EUR to ¥163/EUR, which will be applied to the forecasts for the full year.

In light of these trends in earnings and changes in foreign exchange assumptions, we have revised the full-year consolidated earnings forecasts.

The differences from the full-year consolidated earnings forecasts for the fiscal year ending December 31, 2024 announced on February 7, 2024 are as follows.

(Full year)

	Revenue	Core operating profit	Profit before tax	Profit attributable to owners of parent	Basic earnings per share
	(Millions of yen)	(Millions of yen)	(Millions of yen)	(Millions of yen)	(Yen)
Previous forecast (A)	473,000	85,000	85,000	63,000	119.07
Revised forecast (B)	492,000	92,000	92,000	68,000	128.42
Change (B-A)	19,000	7,000	7,000	5,000	–
Rate of change (%)	4.0%	8.2%	8.2%	7.9%	–
Fiscal 2023 results	442,233	96,785	97,246	81,188	151.03

2. Condensed Semi-Annual Consolidated Financial Statements and Significant Notes Thereto

(1) Condensed Semi-Annual Consolidated Statement of Financial Position

(Millions of yen)

	As of December 31, 2023	As of June 30, 2024
Assets		
Non-current assets		
Property, plant and equipment	94,508	104,301
Goodwill	140,450	182,769
Intangible assets	62,918	113,894
Investments accounted for using equity method	12,357	14,646
Other financial assets	33,374	37,765
Retirement benefit asset	15,655	15,949
Deferred tax assets	49,538	50,210
Other non-current assets	6,018	7,055
Total non-current assets	414,818	526,589
Current assets		
Inventories	71,363	77,370
Trade and other receivables	119,082	126,274
Other financial assets	1,923	1,463
Other current assets	15,673	27,178
Cash and cash equivalents	403,083	311,135
Total current assets	611,124	543,420
Total assets	1,025,942	1,070,009

(1) Condensed Semi-Annual Consolidated Statement of Financial Position (continued)

(Millions of yen)

	As of December 31, 2023	As of June 30, 2024
Equity		
Share capital	26,745	26,745
Capital surplus	464,731	464,640
Treasury shares	(2,933)	(29,941)
Retained earnings	338,764	361,077
Other components of equity	9,112	40,167
Total equity attributable to owners of parent	836,418	862,688
Total equity	836,418	862,688
Liabilities		
Non-current liabilities		
Liabilities from application of equity method	13,966	11,345
Retirement benefit liability	293	405
Provisions	8,439	6,657
Deferred tax liabilities	428	515
Other financial liabilities	16,111	20,302
Other non-current liabilities	17,049	13,697
Total non-current liabilities	56,287	52,920
Current liabilities		
Trade and other payables	92,983	114,745
Provisions	2,379	3,156
Other financial liabilities	8,136	5,045
Income taxes payable	4,022	3,367
Other current liabilities	25,718	28,088
Total current liabilities	133,237	154,401
Total liabilities	189,524	207,321
Total equity and liabilities	1,025,942	1,070,009

(2) Condensed Semi-Annual Consolidated Statement of Profit or Loss and Condensed Semi-Annual Consolidated Statement of Comprehensive Income

Condensed Semi-Annual Consolidated Statement of Profit or Loss

(Millions of yen)

	January 1, 2023 to June 30, 2023	January 1, 2024 to June 30, 2024
Revenue	199,209	232,974
Cost of sales	(47,046)	(59,467)
Gross profit	152,163	173,506
Selling, general and administrative expenses	(82,433)	(83,234)
Research and development expenses	(33,654)	(49,245)
Share of profit (loss) of investments accounted for using equity method	1,391	3,109
Other income	500	4,398
Other expenses	(14,167)	(4,661)
Finance income	2,294	3,566
Finance costs	(48)	(917)
Profit before tax	26,046	46,522
Income tax expense	(4,401)	(8,745)
Profit	21,646	37,777
Profit attributable to		
Owners of parent	21,646	37,777
Earnings per share		
Basic earnings per share (Yen)	40.27	70.76
Diluted earnings per share (Yen)	40.26	70.75

Condensed Semi-Annual Consolidated Statement of Comprehensive Income

(Millions of yen)

	January 1, 2023 to June 30, 2023	January 1, 2024 to June 30, 2024
Profit	21,646	37,777
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	433	1,185
Remeasurements of defined benefit plans	–	127
Total of items that will not be reclassified to profit or loss	433	1,312
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	24,010	28,015
Cash flow hedges	–	1,798
Share of other comprehensive income of investments accounted for using equity method	66	96
Total of items that may be reclassified to profit or loss	24,076	29,909
Other comprehensive income	24,508	31,222
Comprehensive income	46,154	68,998
Comprehensive income attributable to		
Owners of parent	46,154	68,998

(3) Condensed Semi-Annual Consolidated Statement of Changes in Equity

January 1, 2023 to June 30, 2023

(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, 2023	26,745	464,434	(3,177)	285,842	219	(12,247)
Profit	–	–	–	21,646	–	–
Other comprehensive income	–	–	–	–	–	24,076
Total comprehensive income	–	–	–	21,646	–	24,076
Dividends of surplus	–	–	–	(14,512)	–	–
Purchase of treasury shares	–	–	(6)	–	–	–
Disposal of treasury shares	–	34	74	–	–	–
Share-based remuneration transactions	–	195	130	–	(108)	–
Transfer from other components of equity to retained earnings	–	–	–	182	–	–
Total transactions with owners	–	229	199	(14,329)	(108)	–
Balance at June 30, 2023	26,745	464,663	(2,978)	293,158	110	11,829

	Equity attributable to owners of parent					Total equity
	Other components of equity				Total	
	Financial assets measured at fair value through other comprehensive income	Remeasure-ments of defined benefit plans	Cash flow hedges	Total		
Balance at January 1, 2023	1,010	–	–	(11,018)	762,826	762,826
Profit	–	–	–	–	21,646	21,646
Other comprehensive income	433	–	–	24,508	24,508	24,508
Total comprehensive income	433	–	–	24,508	46,154	46,154
Dividends of surplus	–	–	–	–	(14,512)	(14,512)
Purchase of treasury shares	–	–	–	–	(6)	(6)
Disposal of treasury shares	–	–	–	–	109	109
Share-based remuneration transactions	–	–	–	(108)	216	216
Transfer from other components of equity to retained earnings	(182)	–	–	(182)	–	–
Total transactions with owners	(182)	–	–	(291)	(14,193)	(14,193)
Balance at June 30, 2023	1,260	–	–	13,199	794,787	794,787

(3) Condensed Semi-Annual Consolidated Statement of Changes in Equity (continued)

January 1, 2024 to June 30, 2024

(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, 2024	26,745	464,731	(2,933)	338,764	102	8,823
Profit	–	–	–	37,777	–	–
Other comprehensive income	–	–	–	–	–	28,111
Total comprehensive income	–	–	–	37,777	–	28,111
Dividends of surplus	–	–	–	(15,591)	–	–
Purchase of treasury shares	–	–	(27,047)	–	–	–
Disposal of treasury shares	–	(135)	67	–	–	–
Share-based remuneration transactions	–	44	(28)	–	(39)	–
Transfer from other components of equity to retained earnings	–	–	–	127	–	–
Total transactions with owners	–	(91)	(27,008)	(15,463)	(39)	–
Balance at June 30, 2024	26,745	464,640	(29,941)	361,077	64	36,934

	Equity attributable to owners of parent					Total equity
	Other components of equity				Total	
	Financial assets measured at fair value through other comprehensive income	Remeasure-ments of defined benefit plans	Cash flow hedges	Total		
Balance at January 1, 2024	1,984	–	(1,798)	9,112	836,418	836,418
Profit	–	–	–	–	37,777	37,777
Other comprehensive income	1,185	127	1,798	31,222	31,222	31,222
Total comprehensive income	1,185	127	1,798	31,222	68,998	68,998
Dividends of surplus	–	–	–	–	(15,591)	(15,591)
Purchase of treasury shares	–	–	–	–	(27,047)	(27,047)
Disposal of treasury shares	–	–	–	–	(68)	(68)
Share-based remuneration transactions	–	–	–	(39)	(23)	(23)
Transfer from other components of equity to retained earnings	–	(127)	–	(127)	–	–
Total transactions with owners	–	(127)	–	(166)	(42,728)	(42,728)
Balance at June 30, 2024	3,169	–	–	40,167	862,688	862,688

(4) Condensed Semi-Annual Consolidated Statement of Cash Flows

(Millions of yen)

	January 1, 2023 to June 30, 2023	January 1, 2024 to June 30, 2024
Cash flows from operating activities		
Profit before tax	26,046	46,522
Depreciation and amortization	9,856	12,072
Impairment losses (reversal of impairment losses)	9,389	255
Increase (decrease) in provisions	867	(1,358)
Share of loss (profit) of investments accounted for using equity method	(1,391)	(3,109)
Foreign exchange loss (gain)	12,015	6,335
Decrease (increase) in inventories	(4,767)	(3,101)
Decrease (increase) in trade receivables	7,040	1,965
Increase (decrease) in trade payables	488	(2,658)
Increase (decrease) in contract liabilities	(4,052)	(5,848)
Income taxes paid	(1,513)	(5,828)
Other	6,364	1,604
Net cash provided by (used in) operating activities	60,344	46,851
Cash flows from investing activities		
Purchase of property, plant and equipment	(10,914)	(13,099)
Proceeds from sale of property, plant and equipment	–	3,357
Purchase of intangible assets	(4,822)	(21,882)
Purchase of shares of subsidiaries resulting in change in scope of consolidation	–	(48,196)
Proceeds from redemption of bonds of subsidiaries and associates	2,000	–
Other	(221)	(681)
Net cash provided by (used in) investing activities	(13,958)	(80,501)
Cash flows from financing activities		
Redemption of bonds with share acquisition rights	–	(9,621)
Repayments of lease liabilities	(1,722)	(1,848)
Purchase of treasury shares	(6)	(27,047)
Decrease (increase) in deposits for the purchase of treasury shares	–	(8,959)
Dividends paid	(14,512)	(15,591)
Other	172	(163)
Net cash provided by (used in) financing activities	(16,068)	(63,229)
Effect of exchange rate changes on cash and cash equivalents	2,619	4,931
Net increase (decrease) in cash and cash equivalents	32,936	(91,948)
Cash and cash equivalents at beginning of period	339,194	403,083
Cash and cash equivalents at end of period	372,131	311,135

(5) Notes to Condensed Semi-Annual Consolidated Financial Statements

Notes on going concern assumption

No applicable items.

Segment information

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

Cash flow information

The ¥9,621 million in redemption of bonds with share acquisition rights during the six months ended June 30, 2024 were expenditures related to bonds with share acquisition rights issued by Orchard Therapeutics plc before the business combination.

Subsequent events

Transfer of ownership interest in a subsidiary

The Company licenses and, through its partners, conducts sales activities for the Company's products, including established medicines, in the Asian region. As the Company has determined that ensuring a continuous supply of these products for patients who need them provides a benefit to the patients and the medical institutions and other relevant parties and will also lead to sustainable growth of the Company, the Company resolved, at the Board of Directors meeting held on August 1, 2024, to reorganize the business related to the APAC region. As part of this reorganization, the Company resolved to transfer the equity interest of Kyowa Kirin China Pharmaceutical Co., Ltd. that is held by the Company's consolidated subsidiary Kyowa Kirin Asia Pacific Pte. Ltd. to a special purpose company to be newly established, and to transfer all of the shares of the company to Hong Kong WinHealth Pharma Group Co. Limited through a sale of the shares. On the same date, a share transfer agreement was concluded with Hong Kong WinHealth Pharma Group Co. Limited. The planned execution date of the share transfer is September 30, 2024.

The impact of this transfer of ownership interest on the Company's consolidated financial results is currently being examined.

Liquidation of a subsidiary

The Company resolved, at the Board of Directors meeting held on August 1, 2024, to reorganize the business related to the APAC region, and accompanying this reorganization, to dissolve and liquidate the Company's consolidated subsidiary Kyowa Kirin Asia Pacific Pte. Ltd. As the liquidation is scheduled to be completed around 2026, the impact on the Company's consolidated financial results has not been determined.