



Kyowa Kirin Co., Ltd.

Consolidated Financial Summary (IFRS) Fiscal 2021 Third Quarter (January 1, 2021 – September 30, 2021)

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

SUMMARY OF CONSOLIDATED FINANCIAL STATEMENTS (IFRS) for Nine Months Ended September 30, 2021

November 1, 2021

Company Name: Kyowa Kirin Co., Ltd. Listed Exchanges: 1st Section of the Tokyo Stock Exchange
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Scheduled date of submission of Quarterly Securities Report: November 1, 2021

Scheduled start date of dividend payment: -

Appendix materials to accompany the quarterly financial report: Yes

Quarterly results presentation meeting: Yes (for institutional investors and securities analysts)

(Millions of yen rounded off)

1. Consolidated Financial Results for the Nine Months Ended September 30, 2021

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

	Revenue		Core operating profit		Profit before tax		Profit	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended								
September 30, 2021	253,969	8.5	46,820	(7.6)	41,890	(5.2)	32,908	(12.2)
September 30, 2020	234,004	3.8	50,693	10.8	44,183	32.1	37,489	(33.4)

Total comprehensive income: Nine months ended September 30, 2021: ¥38,892 million; 27.8%

Nine months ended September 30, 2020: ¥30,429 million; (44.1)%

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
	Millions of yen	%	Yen	Yen
Nine months ended				
September 30, 2021	32,908	(12.2)	61.25	61.22
September 30, 2020	37,489	(33.4)	69.80	69.75

(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
	Millions of yen	Millions of yen	Millions of yen	%
As of				
September 30, 2021	856,804	713,274	713,274	83.2
December 31, 2020	801,290	698,396	698,396	87.2

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, 2020	—	22.00	—	22.00	44.00
Fiscal year ending December 31, 2021	—	23.00	—		
Fiscal year ending December 31, 2021 (Forecast)				23.00	46.00

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

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2021 (from January 1, 2021 to December 31, 2021)

(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	351,000	10.3	65,000	8.4	64,000	22.5	50,000	6.3	50,000	6.3	93.08

Note: Changes to the earnings forecasts most recently announced: None

* 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 September 30, 2021	540,000,000 shares
As of December 31, 2020	540,000,000 shares

b. Number of treasury shares

As of September 30, 2021	2,684,635 shares
As of December 31, 2020	2,823,975 shares

c. Average number of shares during the period

Nine months ended September 30, 2021	537,256,814 shares
Nine months ended September 30, 2020	537,089,478 shares

* Quarterly financial results reports are exempt from quarterly 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.

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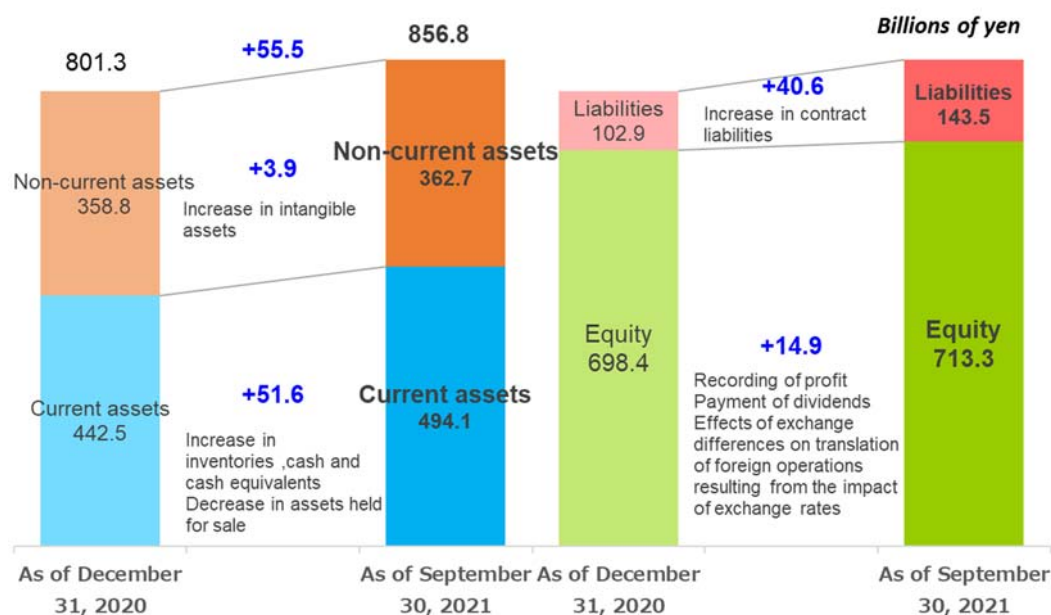
1. Operating Results and Financial Statements

(1) Summary of Consolidated Financial Position

(Billions of yen)

	As of December 31, 2020	As of September 30, 2021	Year-on-year change
Assets	801.3	856.8	55.5
Non-current assets	358.8	362.7	3.9
Current assets	442.5	494.1	51.6
Liabilities	102.9	143.5	40.6
Equity	698.4	713.3	14.9
Ratio of equity attributable to owners of parent to total assets (%)	87.2%	83.2%	(3.9)%

- Assets as of September 30, 2021, were ¥856.8 billion, an increase of ¥55.5 billion compared to the end of the previous fiscal year.
 - Non-current assets increased by ¥3.9 billion to ¥362.7 billion, due mainly to an increase in intangible assets associated with in-licensing of development products, despite impairment of marketing rights, a decrease from sale of investment securities, etc.
 - Current assets increased by ¥51.6 billion to ¥494.1 billion, due mainly to an increase in cash and cash equivalents from the proceeds from sale of assets held for sale (shares of Hitachi Chemical Diagnostics Systems Co., Ltd.) and proceeds from upfront payment received from Amgen Inc. based on an agreement for joint development and commercialization of KHK4083, as well as an increase in inventories, despite a decrease in assets held for sale.
- Liabilities as of September 30, 2021, were ¥143.5 billion, an increase of ¥40.6 billion compared to the end of the previous fiscal year, due mainly to an increase in contract liabilities accompanying the conclusion of an agreement with Amgen Inc.
- Equity as of September 30, 2021, was ¥713.3 billion, an increase of ¥14.9 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, etc. The ratio of equity attributable to owners of parent to total assets as of the end of the third quarter was 83.2%, a decrease of 3.9 percentage points compared to the end of the previous fiscal year.



(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)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change	Year-on-year (%)
Revenue	234.0	254.0	20.0	8.5%
Core operating profit	50.7	46.8	(3.9)	(7.6)%
Profit before tax	44.2	41.9	(2.3)	(5.2)%
Profit attributable to owners of parent	37.5	32.9	(4.6)	(12.2)%

< Average exchange rates for each period >

Currency	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change
USD (USD/¥)	¥108	¥108	¥-
GBP (GBP/¥)	¥137	¥149	Up ¥12
CNY (CNY/¥)	¥15.4	¥16.6	Up ¥1.2

For the nine months ended September 30, 2021 (January 1, 2021 to September 30, 2021), revenue was ¥254.0 billion (up 8.5% compared to the same period of the previous fiscal year), and core operating profit was ¥46.8 billion (down 7.6%). Profit attributable to owners of parent was ¥32.9 billion (down 12.2%).

- The increase in revenue was the result of steady growth of global strategic products in North America and EMEA and higher revenue year on year in Asia, mainly in China, despite lower revenue in Japan. The positive effect on revenue from foreign exchange was ¥4.6 billion.
- The decrease in core operating profit was the result of increases in selling, general and administrative expenses, and research and development expenses, despite an increase in gross profit due to an increase in overseas revenue. The positive effect on core operating profit from foreign exchange was ¥1.1 billion.
- Profit attributable to owners of parent decreased as a result of an increase in income tax expense in addition to a decrease in core operating profit, despite a decrease in other expenses.

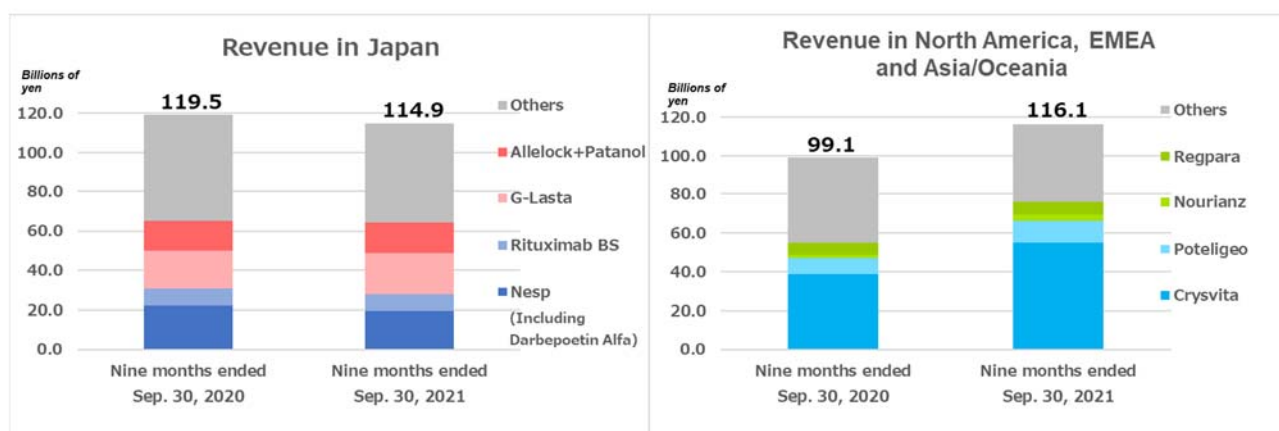
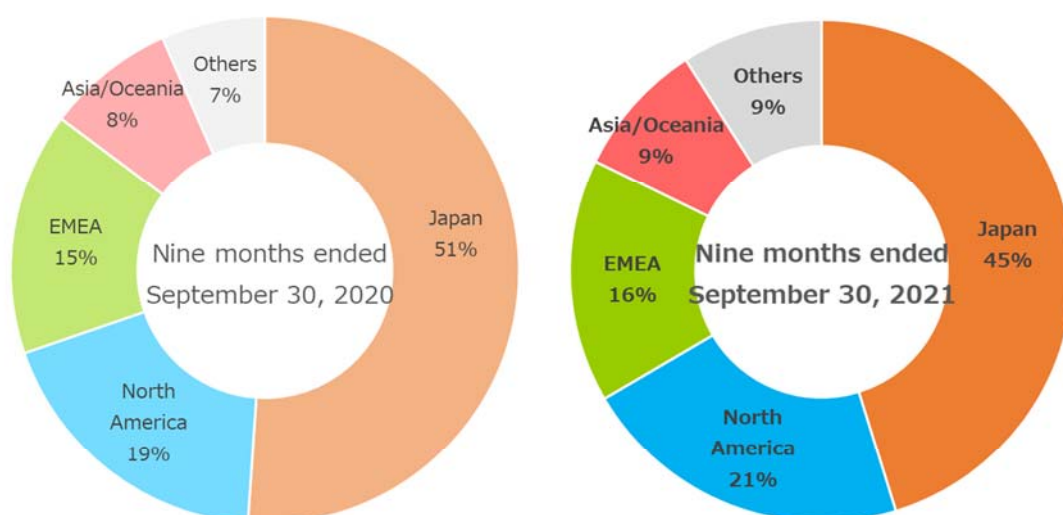
2) Revenue by regional control function

(Billions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change	Year-on-year (%)
Japan	119.5	114.9	(4.7)	(3.9)%
North America	43.7	54.2	10.5	24.1%
EMEA	36.3	39.8	3.6	9.8%
Asia/Oceania	19.1	22.1	2.9	15.4%
Others	15.4	23.0	7.6	49.2%
Total consolidated revenue	234.0	254.0	20.0	8.5%

- Notes:
1. Revenue by regional control function is classified based on consolidated revenue from products of regional control functions in the One Kyowa Kirin structure (a global management structure with axes combining four regions – Japan, North America, EMEA, and Asia/Oceania – and the functions needed by a global specialty pharmaceutical company).
 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



< Overview of Japan >

(Billions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change	Year-on-year (%)
Darbepoetin Alfa Injection Syringe [KKF]	18.6	16.7	(2.0)	(10.5)%
G-Lasta	19.6	21.2	1.6	8.2%
Romiplate	5.8	4.9	(0.9)	(15.8)%
Patanol	8.7	9.2	0.5	5.5%
Crysvita	2.4	5.1	2.7	113.2%
(Reference) Asacol, Minirinmelt and Desmopressin	1.9	–	(1.9)	(100.0)%

- Revenue in Japan decreased year on year due to the impact of the expiration of co-marketing agreements for some products, in addition to the impact of the reductions in drug price standards implemented in April 2020 and April 2021, despite the growth in sales of new product groups, such as Crysvita[®], a treatment for FGF23-related diseases.
 - Revenue from Darbepoetin Alfa Injection Syringe [KKF], a renal anemia treatment drug, decreased due to the impact of the market penetration of rival products.
 - Firm growth in revenue was realized for G-Lasta[®], an agent for decreasing the incidence of febrile neutropenia.
 - Revenue from ROMIPLATE[®], a treatment for chronic idiopathic thrombocytopenic purpura, decreased as a result of adjusting the shipments to distributors (June 2020 to March 2021).
 - Revenue from Patanol[®], anti-allergy eye drops, increased as a result of higher pollen counts.
 - Crysvita[®], a treatment for FGF23-related diseases, has been penetrating the market favorably since their launch in 2019.
 - Revenue from ASACOL[®], an ulcerative colitis treatment drug, and MINIRINMELT[®] and DESMOPRESSIN, which are treatments for central diabetes insipidus, decreased as a result of the Company discontinuing its sales of ASACOL[®] on March 31, 2020 and MINIRINMELT[®] and DESMOPRESSIN on April 27, 2020.

< Overview of North America, EMEA and Asia/Oceania >

(Billions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change	Year-on-year (%)
Crysvita	38.5	55.1	16.5	42.9%
Poteligeo	8.4	11.0	2.5	29.9%
Nourianz	1.7	3.1	1.4	80.1%
Regpara	6.1	6.7	0.6	10.6%
Abstral	7.6	6.3	(1.4)	(18.1)%

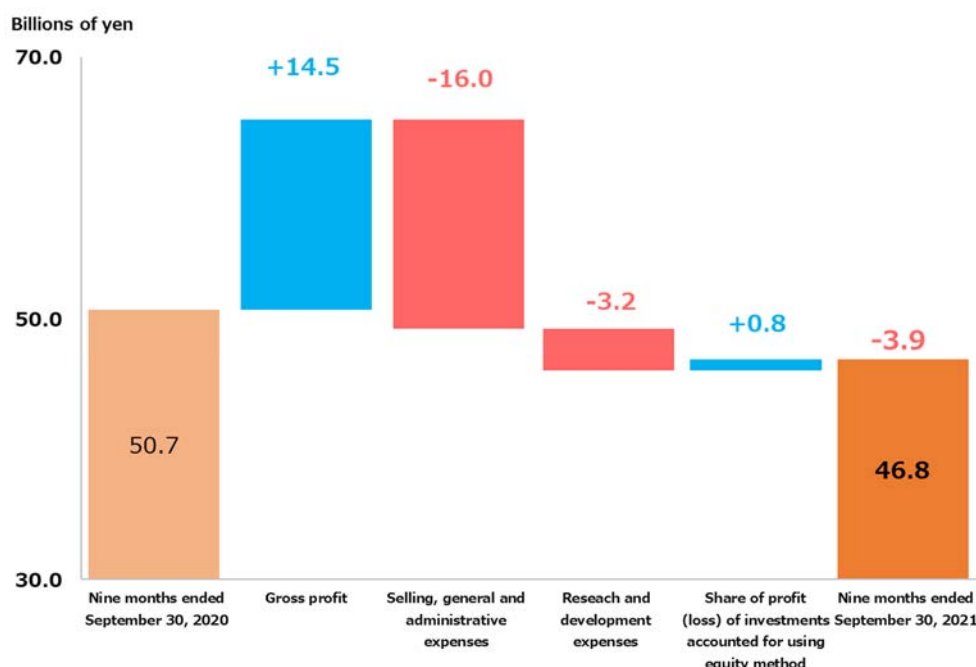
- Revenue in North America increased year on year due to the steady growth of global strategic products.
 - Revenue from Crysvita[®], a treatment for X-linked hypophosphatemia, has been growing steadily since its launch in 2018. Approval for additional indication for treatment of tumor induced osteomalacia was acquired in June 2020.
 - Firm growth in revenue was realized for POTELIGEO[®], an anticancer agent.
 - 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 steady growth of global strategic products.
 - Revenue from Crysvida[®], a treatment for X-linked hypophosphatemia, has been growing steadily as the number of countries where it has been released has been increasing since its launch in 2018. Approval for sale with the extended indication for older adolescents and adults was acquired in September 2020.
 - Sales of POTEIGEO[®], an anticancer agent, was launched in June 2020 in Germany, and it has been penetrating the market favorably as the number of countries where it has been released has been increasing.
 - Revenue from Abstral[®], a treatment for cancer pain, decreased year on year due mainly to the impact of the market penetration of generics and shipping schedule adjustments.
- Revenue in Asia/Oceania increased year on year, mainly in China.
 - Revenue from REGPARA[®], a treatment for secondary hyperparathyroidism, increased year on year in China.

< Revenue from Others >

- Revenue from Others increased year on year.
 - Technology out-licensing increased in conjunction with the conclusion of an agreement with Amgen Inc. to jointly develop and commercialize KHK4083, anti-OX40 fully human monoclonal antibody for the treatment of atopic dermatitis, with potential in other autoimmune diseases, and the conclusion of an agreement to grant Aevi Genomic Medicine, LLC the rights to develop, manufacture and commercialize the human anti-LIGHT monoclonal antibody for all indications worldwide, in addition to an increase in royalties revenue from AstraZeneca in relation to benralizumab.

3) Core operating profit

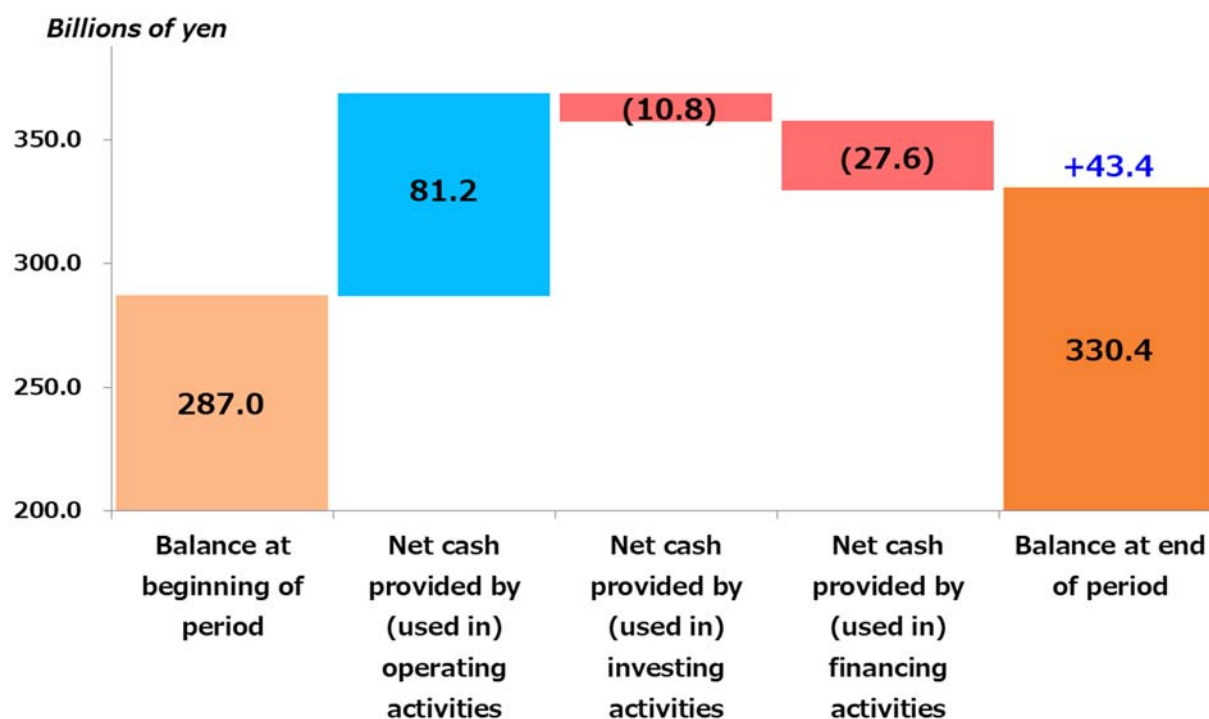


- Core operating profit decreased compared to the same period of the previous fiscal year due mainly to increases in selling, general and administrative expenses, and research and development expenses in order to maximize the value of global strategic products and rapidly establish competitive global business bases, despite an increase in gross profit due to an increase in overseas revenue mainly from global strategic products.

(3) Summary of Consolidated Cash Flows*(Billions of yen)*

	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year change	Year-on-year (%)
Net cash provided by (used in) operating activities	31.9	81.2	49.3	154.8%
Net cash provided by (used in) investing activities	258.7	(10.8)	(269.5)	–
Net cash provided by (used in) financing activities	(25.9)	(27.6)	(1.6)	6.3%
Cash and cash equivalents at beginning of period	20.8	287.0	266.3	–
Cash and cash equivalents at end of period	285.0	330.4	45.4	15.9%

- Cash and cash equivalents as of September 30, 2021, were ¥330.4 billion, an increase of ¥43.4 billion compared with the balance of ¥287.0 billion as of December 31, 2020. The main contributing factors affecting cash flow during the nine months ended September 30, 2021 were as follows:
- Net cash provided by operating activities was ¥81.2 billion, compared with net cash provided by operating activities of ¥31.9 billion in the same period of the previous fiscal year. Major inflows included increase (decrease) in contract liabilities of ¥41.2 billion, which included proceeds of USD400 million from upfront payment received from Amgen Inc. based on an agreement for joint development and commercialization of KHK4083, in addition to profit before tax of ¥41.9 billion and depreciation and amortization of ¥14.1 billion. Major outflows included income taxes paid of ¥13.9 billion.
- Net cash used in investing activities was ¥10.8 billion, compared with net cash provided by investing activities of ¥258.7 billion in the same period of the previous fiscal year. Major outflows included ¥12.5 billion for purchase of intangible assets and ¥4.9 billion for purchase of property, plant and equipment. Major inflows included proceeds from sale of investments accounted for using equity method of ¥5.1 billion, and proceeds from sale of investment securities of ¥1.8 billion.
- Net cash used in financing activities was ¥27.6 billion, compared with net cash used in financing activities of ¥25.9 billion in the same period of the previous fiscal year. Major outflows included dividends paid of ¥24.2 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 nine months ended September 30, 2021, the Group’s research and development expenses totaled ¥40.8 billion, and our progress in the respective disease fields of our main late-stage development products are as follows. (“◆” indicates the progress made during the third quarter of fiscal 2021.)

Nephrology

RTA 402

- In January 2021, we started a phase III clinical study in Japan for treatment of autosomal dominant polycystic kidney disease.
- ◆ In July 2021, we applied for approval for treatment of Alport Syndrome in Japan.

KHK7791

- In April 2021, we started a phase III clinical study in Japan for treatment of hyperphosphatemia in patients receiving hemodialysis and peritoneal dialysis.

Oncology

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

- In June 2021, we applied for approval of its indication for treatment of mycosis fungoides and Sézary syndrome in China.

KHK2375

- ◆ We conducted a phase II clinical study in Japan for treatment of breast cancer, but the global phase III clinical study (E2112 trial) sponsored by the National Cancer Institute (NCI) in the U.S. that had been proceeding did not achieve its endpoint and, after considering the possibility of an application for approval being accepted in Japan, we have discontinued all subsequent development.

KRN125 (product name in Japan: G-Lasta®)

- In March 2021, the Company filed an application for a partial change of approval indication for the mobilization of hematopoietic stem cells into peripheral blood for allogenic blood stem cell transplantation in Japan.
- ◆ In August 2021, we applied for approval for automated injection device for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy in Japan.
- ◆ In September 2021, we started a phase II clinical study in Japan for the mobilization of hematopoietic stem cells into peripheral blood for autologous peripheral blood stem cell transplantation.

ME-401

- In June 2021, we started the second study arm for treatment of marginal zone lymphoma of the global phase II clinical study.
- ◆ In August 2021, we started a global phase III clinical study for combination therapy with rituximab for patients with relapsed or refractory follicular lymphoma or marginal zone lymphoma.

Immunology and allergy

KHK4083/AMG451

- In June 2021, we concluded an agreement to jointly develop and commercialize KHK4083, for the treatment of atopic dermatitis and several other diseases, with Amgen Inc.

Other

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

- In January 2021, an application for partial change approval for our biologics license regarding its indication for treatment of tumor induced osteomalacia was accepted in Europe. (application filed in December 2020)
- In January 2021, we obtained approval of its indication for treatment of X-linked hypophosphatemic rickets and osteomalacia in China.
- In March 2021, we obtained approval of its indication for treatment of tumor induced osteomalacia in China.

AMG531 (product name in Japan: Romiplate®)











- ◆ In August 2021, we obtained approval of its indication for treatment of patients with aplastic anemia (AA) which is refractory to immunosuppressive therapy or immunosuppressive therapy being not suitable in South Korea.

R&D pipeline



















 antibody
  protein
  small molecule
  New Molecular Entity
  Updated since Dec. 31, 2020
  Updated since Jun. 30, 2021

Nephrology

As of September 30, 2021



Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
 KHK7580 Evocalcet Oral	Calcimimetic	Secondary Hyperparathyroidism	CN Asia						[Mitsubishi Tanabe Pharma] product name in Japan: Orkedia
 ©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 Oral	NHE3 Inhibitor	Hyperphosphatemia in Patients on Dialysis	JP						[Ardelyx]

Oncology




Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
 KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	CH						[In-House] POTELLIGENT® product name in Japan, U.S. and Europe: Poteligeo
			SA AU						
			KR						
			CN CA 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						[Kirin-Amgen] 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						
 ©KHK2455 Oral	IDO1 Inhibitor	Solid Tumor	NA						[In-House] Combination with KW-0761
		Urothelial carcinoma	NA						[In-House] Combination with avelumab
			Europe						
 ©ME-401 Zandelisib Oral	PI3Kδ Inhibitor	Follicular Lymphoma and Marginal Zone Lymphoma	JP NA Europe Asia Oceania others						[MEI Pharma] Combination with rituximab
		Follicular Lymphoma and Marginal Zone Lymphoma	NA Europe Asia Oceania						[MEI Pharma]
		Indolent B-cell Non-Hodgkin's Lymphoma	JP						
		B-cell malignancies	NA						[MEI Pharma] Monotherapy, combination with rituximab and combination with zanubrutinib

Since the development of KHK2375 for breast cancer was discontinued, the relevant information was deleted from this table.





Immunology/Allergy

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
 KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Ankylosing Spondylitis	TW	→					[Kirin-Amgen] product name in Japan: Lumicef
			MY	→					
		Systemic Sclerosis	JP	→					
		Palmoplantar Pustulosis	JP	→					
 ©KHK4083/AMG 451 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.

Central Nervous System

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
 KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Europe	→					[In-House] product name in Japan: Nouriastr, product name in U.S.: Nourianz
 ©KW-6356 Oral	Adenosine A _{2A} Receptor Antagonist/Inverse Agonist	Parkinson's Disease	JP	→					[In-House]
 ©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					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
 KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	AU	→					[In-House] Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU product name in Japan, U.S. and Europe: Crysvisa
			CN BH SA SG	→					
			TL MY	→					
		Tumor Induced Osteomalacia (TIO)	CA	→					
			CN	→					
			Europe	→					
				→					
 AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Treatment of Aplastic anemia (AA) which is refractory to immunosuppressive therapy or immunosuppressive therapy being not suitable	KR	→					[Kirin-Amgen] product name in Japan: Romiplate
		Immune Thrombocytopenia (ITP)	CN	→					
		Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	JP Asia	→					
 KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Europe	→					[In-House] product name in Japan: Acoalan
 KHK4951		Wet Age-Related Macular Degeneration	JP	→					[In-House]

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

No revisions have been made to the consolidated earnings forecasts announced on February 4, 2021.

2. Condensed Quarterly Consolidated Financial Statements and Significant Notes Thereto**(1) Condensed Quarterly Consolidated Statement of Financial Position***(Millions of yen)*

	As of December 31, 2020	As of September 30, 2021
Assets		
Non-current assets		
Property, plant and equipment	76,012	74,940
Goodwill	132,695	135,217
Intangible assets	75,027	78,628
Investments accounted for using equity method	9,475	11,353
Other financial assets	17,323	13,287
Retirement benefit asset	14,674	13,614
Deferred tax assets	33,133	34,968
Other non-current assets	468	688
Total non-current assets	358,808	362,695
Current assets		
Inventories	51,281	59,219
Trade and other receivables	92,287	91,756
Other financial assets	636	690
Other current assets	6,161	12,005
Cash and cash equivalents	287,019	330,439
Subtotal	437,385	494,109
Assets held for sale	5,097	–
Total current assets	442,482	494,109
Total assets	801,290	856,804

(1) Condensed Quarterly Consolidated Statement of Financial Position (continued)*(Millions of yen)*

	As of December 31, 2020	As of September 30, 2021
Equity		
Share capital	26,745	26,745
Capital surplus	463,967	464,130
Treasury shares	(3,545)	(3,391)
Retained earnings	226,639	234,514
Other components of equity	(15,410)	(8,724)
Total equity attributable to owners of parent	698,396	713,274
Total equity	698,396	713,274
Liabilities		
Non-current liabilities		
Retirement benefit liability	216	313
Provisions	7,823	7,756
Deferred tax liabilities	92	290
Other financial liabilities	13,159	13,958
Other non-current liabilities	854	33,505
Total non-current liabilities	22,145	55,821
Current liabilities		
Trade and other payables	54,867	55,196
Provisions	2,027	1,588
Other financial liabilities	5,123	4,876
Income taxes payable	4,661	2,249
Other current liabilities	14,070	23,800
Total current liabilities	80,749	87,709
Total liabilities	102,894	143,529
Total equity and liabilities	801,290	856,804

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

(Millions of yen)

	January 1, 2020 to September 30, 2020	January 1, 2021 to September 30, 2021
Revenue	234,004	253,969
Cost of sales	(58,639)	(64,108)
Gross profit	175,365	189,861
Selling, general and administrative expenses	(88,141)	(103,507)
Research and development expenses	(37,025)	(40,835)
Share of profit (loss) of investments accounted for using equity method	494	1,300
Other income	986	736
Other expenses	(8,697)	(5,773)
Finance income	1,405	756
Finance costs	(205)	(649)
Profit before tax	44,183	41,890
Income tax expense	(6,694)	(8,982)
Profit	37,489	32,908
Profit attributable to Owners of parent	37,489	32,908
Earnings per share		
Basic earnings per share (Yen)	69.80	61.25
Diluted earnings per share (Yen)	69.75	61.22

Condensed Quarterly Consolidated Statement of Comprehensive Income*(Millions of yen)*

	January 1, 2020 to September 30, 2020	January 1, 2021 to September 30, 2021
Profit	37,489	32,908
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(735)	(1,491)
Share of other comprehensive income of investments accounted for using equity method	(73)	–
Total of items that will not be reclassified to profit or loss	(808)	(1,491)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(6,165)	7,328
Share of other comprehensive income of investments accounted for using equity method	(87)	146
Total of items that may be reclassified to profit or loss	(6,251)	7,474
Other comprehensive income	(7,059)	5,983
Comprehensive income	30,429	38,892
Comprehensive income attributable to		
Owners of parent	30,429	38,892

(3) Condensed Quarterly Consolidated Statement of Changes in Equity

January 1, 2020 to September 30, 2020

(Millions of yen)

	Equity attributable to owners of parent					
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Share acquisition rights	Exchange differences on translation of foreign operations
Balance at January 1, 2020	26,745	463,893	(3,792)	201,253	751	(13,647)
Profit	–	–	–	37,489	–	–
Other comprehensive income	–	–	–	–	–	(6,251)
Total comprehensive income	–	–	–	37,489	–	(6,251)
Dividends of surplus	–	–	–	(23,631)	–	–
Purchase of treasury shares	–	–	(9)	–	–	–
Disposal of treasury shares	–	16	163	–	–	–
Share-based remuneration transactions	–	36	60	–	(144)	–
Transfer from other components of equity to retained earnings	–	–	–	(73)	–	–
Total transactions with owners	–	53	215	(23,703)	(144)	–
Balance at September 30, 2020	26,745	463,945	(3,578)	215,038	607	(19,898)

	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	Total		
Balance at January 1, 2020	3,047	–	(9,849)	678,250	678,250	
Profit	–	–	–	37,489	37,489	
Other comprehensive income	(735)	(73)	(7,059)	(7,059)	(7,059)	
Total comprehensive income	(735)	(73)	(7,059)	30,429	30,429	
Dividends of surplus	–	–	–	(23,631)	(23,631)	
Purchase of treasury shares	–	–	–	(9)	(9)	
Disposal of treasury shares	–	–	–	179	179	
Share-based remuneration transactions	–	–	(144)	(48)	(48)	
Transfer from other components of equity to retained earnings	–	73	73	–	–	
Total transactions with owners	–	73	(72)	(23,508)	(23,508)	
Balance at September 30, 2020	2,312	–	(16,980)	685,171	685,171	

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

January 1, 2021 to September 30, 2021

(Millions of yen)

	Equity attributable to owners of parent					
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					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	–	–	–	32,908	–	–
Other comprehensive income	–	–	–	–	–	7,474
Total comprehensive income	–	–	–	32,908	–	7,474
Dividends of surplus	–	–	–	(24,176)	–	–
Purchase of treasury shares	–	–	(17)	–	–	–
Disposal of treasury shares	–	53	103	–	–	–
Share-based remuneration transactions	–	110	69	–	(155)	–
Transfer from other components of equity to retained earnings	–	–	–	(857)	–	–
Total transactions with owners	–	163	154	(25,033)	(155)	–
Balance at September 30, 2021	26,745	464,130	(3,391)	234,514	441	(10,440)

	Equity attributable to owners of parent			Total equity
	Other components of equity		Total	
	Financial assets measured at fair value through other comprehensive income	Total		
Balance at January 1, 2021	1,909	(15,410)	698,396	698,396
Profit	–	–	32,908	32,908
Other comprehensive income	(1,491)	5,983	5,983	5,983
Total comprehensive income	(1,491)	5,983	38,892	38,892
Dividends of surplus	–	–	(24,176)	(24,176)
Purchase of treasury shares	–	–	(17)	(17)
Disposal of treasury shares	–	–	155	155
Share-based remuneration transactions	–	(155)	24	24
Transfer from other components of equity to retained earnings	857	857	–	–
Total transactions with owners	857	703	(24,013)	(24,013)
Balance at September 30, 2021	1,275	(8,724)	713,274	713,274

(4) Condensed Quarterly Consolidated Statement of Cash Flows*(Millions of yen)*

	January 1, 2020 to September 30, 2020	January 1, 2021 to September 30, 2021
Cash flows from operating activities		
Profit before tax	44,183	41,890
Depreciation and amortization	13,768	14,090
Impairment losses (reversal of impairment losses)	2,679	4,907
Increase (decrease) in provisions	3,283	(573)
Share of loss (profit) of investments accounted for using equity method	(494)	(1,300)
Decrease (increase) in inventories	(6,529)	(4,582)
Decrease (increase) in trade receivables	2,882	2,862
Increase (decrease) in trade payables	250	(4,899)
Increase (decrease) in contract liabilities	(1,394)	41,183
Income taxes paid	(26,559)	(13,912)
Other	(207)	1,521
Net cash provided by (used in) operating activities	31,861	81,186
Cash flows from investing activities		
Purchase of property, plant and equipment	(7,827)	(4,898)
Purchase of intangible assets	(19,728)	(12,546)
Purchase of investments accounted for using equity method	(500)	–
Proceeds from sale of investments accounted for using equity method	–	5,097
Proceeds from sale of investment securities	–	1,774
Net decrease (increase) in loans receivable from parent	285,700	–
Other	1,030	(204)
Net cash provided by (used in) investing activities	258,676	(10,777)
Cash flows from financing activities		
Repayments of lease liabilities	(2,372)	(2,583)
Purchase of treasury shares	(9)	(17)
Dividends paid	(23,631)	(24,176)
Other	97	(779)
Net cash provided by (used in) financing activities	(25,914)	(27,555)
Effect of exchange rate changes on cash and cash equivalents	(386)	566
Net increase (decrease) in cash and cash equivalents	264,237	43,420
Cash and cash equivalents at beginning of period	20,762	287,019
Cash and cash equivalents at end of period	285,000	330,439

(5) Notes to Condensed Quarterly Consolidated Financial Statements**Notes on going concern assumption**

No applicable items.

Changes in presentation

Effective from the first quarter of fiscal 2021, from the perspective of providing greater convenience for users of consolidated financial statements while promoting dialogue with investors and in conjunction with the start of the FY2021-2025 Medium Term Business Plan, the Company has changed the order in which information is presented in the Condensed Quarterly Consolidated Statement of Financial Position, Condensed Quarterly Consolidated Statement of Profit or Loss, Condensed Quarterly Consolidated Statement of Comprehensive Income, Condensed Quarterly Consolidated Statement of Changes in Equity, Condensed Quarterly Consolidated Statement of Cash Flows, and some of Notes to Condensed Quarterly Consolidated Financial Statements. The presentation order has changed from listing the information for the period under review first, then comparative information for the previous fiscal year or the same period of the previous fiscal year, to listing comparative information for the previous fiscal year or the same period of the previous fiscal year first, then the information for the period under review.

Condensed Quarterly Consolidated Statement of Cash Flows

“Increase (decrease) in contract liabilities,” which had previously been included in “Other” of “Cash flows from operating activities” in the nine months ended September 30, 2020, has been listed independently from the nine months ended September 30, 2021 because its monetary importance has increased. To reflect this change in the presentation method, we have reorganized our Condensed Quarterly Consolidated Financial Statements for the nine months ended September 30, 2020.

As a result, in the Condensed Quarterly Consolidated Statement of Cash Flows for the nine months ended September 30, 2020, negative ¥1,601 million presented as “Other” in “Cash flows from operating activities” was reorganized into “Increase (decrease) in contract liabilities” of negative ¥1,394 million and “Other” of negative ¥207 million.

Segment information

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